IN THE COURT OF COMMON PLEAS
FAYETTE COUNTY, OHIO

THE COUNTY OF FAYETTE, OHIO
133 South Main Street, Suite 401
Washington Court House, Ohio 43160;
THE STATE OF OHIO *EX REL.*
PROSECUTING ATTORNEY OF
FAYETTE COUNTY, JESS WEADE
110 E. Court Street Washington Court
House, Ohio, 43160

Plaintiff,

vs.

PURDUE PHARMA L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901

And

PURDUE PHARMA, INC.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901

And

THE PURDUE FREDERICK
COMPANY INC.
One Stamford Forum
201 Tresser Boulevard
Stamford, CT 06901

And

TEVA PHARMACEUTICALS USA,
INC.
c/o Corporate Creations Network Inc.
119 East Court Street
Cincinnati, OH 45202

And

Case Number: CVH20190261

Judge:

Complaint

(Jury Demand Endorsed Hereon)

CEPHALON, INC.
1090 Horsham Road
North Wales, PA 19454

And

JOHNSON & JOHNSON
c/o Terri Johnson
10219 Salineville Road NE
Salineville, OH 43945

And

JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.
c/o CT Corporation System
4400 Easton Commons
Suite 125
Columbus, OH 43219

And

ENDO HEALTH SOLUTIONS INC.
1400 Atwater Drive
Malvern, PA 19355

And

ENDO PHARMACEUTICALS, INC.
c/o CT Corporation System
4400 Easton Commons
Suite 125
Columbus, OH 43219

And

MALLINCKRODT, LLC
c/o CT Corporation System
4400 Easton Commons Suite 125
Columbus, OH 43219-6230

And

MALLINCKRODT, PLC
675 McDonnell Blvd.
St. Louis, MO 63042

And

SPECGX LLC
3600 North Second Street
Saint Louis, MO 63147

And

CARDINAL HEALTH, INC.
c/o CT Corporation System
4400 Easton Commons
Suite 125
Columbus, OH 43219

And

MCKESSON CORPORATION
c/o Corporation Service Company
50 West Broad Street
Suite 1330
Columbus, OH 43215

And

AMERISOURCEBERGEN DRUG
CORPORATION
c/o CT Corporation System
4400 Easton Commons
Suite 125
Columbus, OH 43219

And

WALGREENS BOOTS ALLIANCE
d/b/a WALGREEN CO
The Prentice-Hall Corporation System, Inc.
50 West Broad Street
Suite 1330
Columbus, OH 43215

And

CVS HEALTH CORPORATION
The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

And

CVS INDIANA, L.L.C.
C T Corporation System
150 West Market Street, Suite 800
Indianapolis, IN, 46204, USA

And

CVS PHARMACY, INC.
C T Corp.
1300 E. 9th Street
Cleveland, OH 441140000

And

OHIO CVS STORES, LLC
CT Corporation System
4400 Easton Commons Way
Suite 125
Columbus, OH 43219

JANE DOES 1 – 50

Defendants.

PRELIMINARY STATEMENT

1. Plaintiff the County of Fayette, Ohio, by and through the Fayette County Prosecutor's Office (the "County") brings this action to prevent future harm and to redress past wrongs, against Defendants: Purdue Pharma, L.P., Purdue Pharma, Inc., the Purdue Frederick Company Inc., Teva Pharmaceuticals USA, Cephalon, Inc., Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica Inc., Johnson & Johnson, Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Mallinckrodt, plc, Mallinckrodt, LLC; SpecGx LLC, AmerisourceBergen Drug Corporation, Cardinal Health, Inc., McKesson Corporation, CVS Health Corporation, CVS Indiana, LLC, CVS Pharmacy, Inc., Ohio CVS Stores, LLC, Walgreens Boots Alliance d/b/a Walgreen Co. (collectively, "Defendants").

2. This suit takes aim at the two primary causes of the opioid crisis: (a) a marketing scheme involving the false and deceptive marketing of prescription opioids, which was designed to dramatically increase the demand for and sale of opioids and opioid prescriptions; and (b) a supply chain scheme, pursuant to which the various entities in the supply chain, including the wholesale distributors and pharmacies, failed to design and operate systems to identify suspicious orders of prescription opioids, maintain effective controls against diversion, and halt suspicious orders when they were identified, thereby contributing to the oversupply of such drugs and fueling an illegal secondary market.

3. Defendants Purdue Pharma, L.P., Purdue Pharma Inc., and the Purdue Frederick Company Inc., (collectively "Purdue"), Teva Pharmaceuticals USA, Inc. and Cephalon, Inc. (collectively, "Teva"), Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica Inc. (collectively "Janssen"), Endo Health Solutions Inc., and Endo Pharmaceuticals Inc. (collectively "Endo"), and Mallinckrodt, LLC, Mallinckrodt, plc, and SpecGx LLC (collectively, "Mallinckrodt") manufacture, market, and sell prescription opioid pain

medications, including the brand-name drugs OxyContin, Butrans, Hysingla ER, Actiq, Fentora, Opana/Opana ER, Percodan, Percocet, Zydone, Nucynta/Nucynta ER, Duragesic, Exalgo, and Xartemis XR. These Defendants are collectively referred to as the "Marketing Defendants."

4. Nationwide, Defendants AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation account for approximately 90% of all revenues from prescription drug distribution. Known colloquially as the "Big Three," the Wholesaler Defendants dominate the wholesale drug distribution market, including, upon information and belief, in the County. During the relevant time period, CVS Health Corporation, CVS Indiana, LLC, CVS Pharmacy, Inc., Ohio CVS Stores, LLC, and Walgreens Boots Alliance, Inc. a/k/a Walgreen Co. (the "Chain Pharmacies") filled two positions on the opioid supply chain: distributor, delivering opioids to their own pharmacies, and dispenser, filling prescriptions of opioids through their own pharmacies and delivering opioids to the ultimate consumers. From these positions, the "Big Three" and the Chain pharmacies had unique information and insight into likely diversion of the drugs they supplied and/or dispensed.

5. Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin, and they are regulated as controlled substances. While opioids can dampen the perception of pain, they also can create an addictive, euphoric high. At higher doses, they can slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy will experience withdrawal symptoms—including severe anxiety, nausea, headaches, tremors, delirium, and pain—which are often prolonged, if opioid use is delayed or discontinued. When using opioids continuously, patients grow tolerant to their analgesic effects (i.e. to relief of pain)—requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

6. Because the medical community recognized these dangers, they originally used opioids cautiously and sparingly, typically only for short-term acute pain—where brief use limited the need for escalating doses and the risk of addiction—or for palliative (end-of-life) care.[1] Consequently, the market for prescription opioids was sharply constrained.

7. To expand their market and profits, the Marketing Defendants initiated, and for years have maintained, a deceptive marketing scheme that was intentionally designed to, and effectively did, change the perception of opioids to permit and encourage the use of opioids long-term for widespread chronic conditions like back pain, migraines, and arthritis. Beginning in the mid-1990s Purdue, later joined by the other Marketing Defendants began to promote opioids generally, and their own opioids in particular, as safe, effective, and appropriate for even long-term use for routine pain conditions.

8. To convince doctors and patients that opioids can and should be used to treat chronic pain, Marketing Defendants had to convince them that long-term opioid use is both safe, by minimizing and understating the risks, especially the serious risk of addiction, and helpful, by overstating the benefits.

9. Marketing Defendants used both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and misleading statements about the risks and benefits of long-term opioid use. In this way, they tainted the sources that doctors and patients relied upon for guidance, including treatment guidelines, continuing medical education programs, medical conferences and seminars, and scientific articles.

10. As part of this strategy, Marketing Defendants misrepresented the risk of addiction for pain patients as modest, manageable, and outweighed by the benefits of opioid use.

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[1] In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

11. Specifically:

a. Marketing Defendants told doctors that patients receiving opioid prescriptions—even patients taking opioids long-term for chronic pain—generally would not become addicted, and that doctors could use screening tools to exclude patients who might.

b. Marketing Defendants told doctors that patients who did appear addicted were not; they were instead "pseudoaddicted" and should be given more opioids.

c. Marketing Defendants told doctors that opioids relieved pain when used long-term, without any studies to support this claim and without disclosing the lack of evidence that opioids were safe or effective long-term or the other risks from long-term use of opioids.

d. Marketing Defendants told doctors that opioids could be taken in higher and higher doses without disclosing the increased risk to patients.

e. Purdue told doctors that OxyContin provided 12 hours of relief when Purdue knew that, for many patients, it did not.

f. Marketing Defendants promised that opioids would improve patients' function and quality of life while trivializing or omitting the many adverse effects of opioids that diminish patients' function and quality of life.

g. Faced with a rising tide of opioid addiction, overdose, and death—precisely the risks that they denied in their marketing—Purdue and Endo falsely promoted their abuse-deterrent opioids as preventing abuse and "safe." But the "abuse-deterrent" features of their opioids could be easily defeated and did not limit oral abuse (the most common form of abuse).

h. Purdue also misrepresented its efforts to rein in the diversion and abuse of opioids, while privately failing to report suspicious prescribing.

12. Marketing Defendants' scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Their deceptive marketing scheme also increased the comfort level of doctors and patients in converting opioids prescribed for acute pain—surgery or injuries, for example—to long-term use by patients who experienced or reported ongoing pain.

13. These Defendants' deceptive marketing caused prescribing not only of their opioids, but of opioids as a class, to skyrocket. According to the Centers for Disease Control and Prevention ("CDC"), opioid prescriptions, as measured by number of prescriptions and morphine milligram equivalent ("MME") per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain.

14. Once Marketing Defendants, created this mass market, Defendants AmerisourceBergen, Cardinal, McKesson, and the Chain Pharmacies (collectively, the "Distributor Defendants") flooded it. The careless, even reckless distribution of opioids into the County correlates directly to skyrocketing addiction, overdose, and death; black markets for diverted prescription opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire—or simply could not afford—prescription opioids. Prescription opioids, at the molecular level and in their effect, closely resemble heroin. Prescription opioids are synthesized from the same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain.

15. Fayette County is no exception to this trend. In fact, prescription rates in the County exceed national averages. According to data from the CDC, Fayette County had more opioid prescriptions than people each year from 2006 to 2015. In 2016, the prescription rate remained shockingly high—99.2 opioid prescriptions dispersed for every 100 people (including children) in the County.

16. As a direct and foreseeable result of Defendants' conduct, the nation and Fayette County are now swept up in what the CDC has called a "public health epidemic" and what the

U.S. Surgeon General has deemed an "urgent health crisis."[2] In 2015, an estimated 2 million Americans were addicted to prescription opioids and 591,000 to heroin. From 1999 to 2016, more than 200,000 people died in the U.S. from overdoses related to prescription opioids—more than the number of Americans who died in the Vietnam War.

17. The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose, and death; black markets for diverted prescription opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire—or simply could not afford—prescription opioids.

18. Thus, rather than compassionately helping patients, this explosion in opioid use—and the resulting explosion of Defendants' profits—has come at the expense of chronic pain patients. According to the director of the CDC, one out of every 550 patients started on opioid therapy die of opioid-related causes a median of 2.6 years after their first opioid prescription.[3] As the then CDC director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[4]

19. As many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in primary care settings struggles with addiction. Prescription opioids at the molecular level and in their effect, closely resemble heroin. Prescription opioids are synthesized from the same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain. And, the link between prescription narcotic painkiller abuse and subsequent and/or

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[2] CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 29, 2014), available at http://www.cdc.gov/washington/testimony/2014/t20140429.htm;. Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at http://turnthetiderx.org.

[3] Frieden and Houry, Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline, NEJM, 4/21/16, at 1503.

[4] *Id.*

simultaneous heroin abuse continues to grow. Across the country, **80% of recent heroin users** have previously used prescription opioids non-medically. As the American Society of Addiction Medicine has explained, four out of five people who try heroin today started with prescription painkillers. In fact, people who are addicted to prescription opioids are 40 times more likely to become addicted to heroin, and the CDC identified addiction to prescription opioids as the strongest risk factor for heroin addiction.

20. This transition became even more dangerous in recent years, as increasingly powerful synthetic opiates began entering communities. Fentanyl—a powerful opioid prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into Ohio communities, including Fayette County. Carfentanil, a powerful derivative of fentanyl that is so strong it is typically used to sedate large wild animals such as elephants, increasingly has been found in heroin and fentanyl sold illicitly.

21. In 2016, the CDC reported that, in contrast to other developed countries, and despite having some of the world's highest spending on medical care, our nation saw life expectancy at birth decline for the second straight year, with the increasing number of people who died of overdoses representing the most significant factor in this alarming trend.

22. Not only has the opioid epidemic been described as the deadliest drug crisis in American history, drug overdoses rose to become the leading cause of death for Americans under 50 years old, eclipsing guns or car accidents. Overdoses have been killing people at a pace faster than the H.I.V. epidemic did at its peak. According to Robert Anderson, who oversees death

statistics at the CDC, "'I don't think we've ever seen anything like this. Certainly not in modern times.'"[5]

23. Ohio is among the states hardest hit by the opioid epidemic. As a recent report from The Ohio State University summarizes, "[o]pioid addiction, abuse, and overdose deaths have become the most pressing public health issue facing Ohio."[6] The rapid rise in overdose deaths in Ohio and the United States as a whole is unprecedented. In 2017, reporting revealed that Ohio now "leads the country in drug overdose deaths per capita, a rate that continues to rise, overwhelming families, communities, and local governments across the state."[7] Overdose deaths have become the leading cause of death for Ohioans under the age of 55, and across all ages, more than two and half times as many people die from drug overdoses as from car accidents. Most of the overdose fatalities in Ohio involved opioids.

24. Fayette County is no exception to this deadly trend. From 2012 to 2014, there were 21 drug-related deaths within the County, which has a population of less than 29,000 people.

25. Overdose deaths are only one consequence. Opioid addiction and misuse also result in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of Narcan or naloxone—the antidote to opioid overdose.

26. The impacts are being felt across generations. Babies are being born addicted to opiates and facing painful withdrawal, as well as potential long-term consequences. Children are being displaced from their homes and raised by relatives or placed in the County's care due to

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[5] Associated Press, *Drug Overdoses Killed 50,000 in U.S., More than Car Crashes*, (Dec. 9, 2016), https://www.nbcnews.com/health/health-news/drug-overdoses-killed-50-000-u-s-more-car-crashes-n694001

[6] C. William Swank Program in Rural-Urban Policy, Taking Measure of Ohio's Opioid Crisis, The Ohio State University (Oct. 2017) at 1.

[7] *Id.*

parents' addiction. The number of children in foster care in the County has more than doubled in the last five years. In 2013, there were 29 children in foster care, and as of March 2017, there were 63 children in foster care in the County. According to the Foster Adoption Coordinator of Fayette County Children Services, the increase in foster care is "very much driven by the opioid and heroin epidemic."[8] About 70% of the children in foster care in the County are in foster care due to the opioid and heroin epidemic.

27. This human suffering cannot be calculated or compensated. But the financial burden to the County is staggering. The County has expanded its services to confront this public health epidemic. Narcan administration alone has saved the lives of hundreds of its residents. The County would further expand its efforts, but the unprecedented epidemic has overwhelmed the County's finances. In addition to the treatment cost, the County is also faced with the increased costs related to drug crimes and other public services responding to the opioid epidemic.

28. As the opioid epidemic took hold and grew, Defendants collected blockbuster profits. In 2012 alone, opioids generated $8 billion in revenue for drug companies. By 2015, sales of opioids grew to approximately $9.6 billion. In the wake of an unprecedented public health epidemic, Defendants have not changed their ways or corrected their past misconduct, but instead are continuing to fuel the crisis.

29. Defendants' conduct has violated, and continues to violate, the Ohio Corrupt Practices Act ("OCPA"), R.C. § 2923.31 *et seq.*, and R.C. § 2307.60, which provides civil liability for injuring another through criminal acts. Additionally, Defendants' conduct constitutes a public nuisance, civil conspiracy, negligence, and unjust enrichment.

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[8] Ashley Bunton, *Opioid Epidemic Has Doubled the Number of Kids in Foster Care*, Record Herald (Mar. 15, 2017), https://www.recordherald.com/news/13235/opioid-epidemic-has-doubled-the-number-of-kids-in-foster-care

30. Accordingly, the County brings this action to hold Defendants accountable for their conduct and seeks abatement, damages, and any other injunctive and equitable relief within this Court's powers to redress and halt these unfair, deceptive, and unlawful practices.

PARTIES

1. Plaintiff

31. The County of Fayette, Ohio ("the County") is a County organized under the laws of the State of Ohio. The County has its seat of government in Washington Court House, Ohio. The Fayette County Prosecutor's Office is located at 72 110 E. Court Street, Washington Court House, Ohio 43160. The County provides many services for its residents, including public assistance, law enforcement services, criminal justice services, addiction and mental health services, and services for families and children.

32. This action is also brought on behalf of the State of Ohio, by and through Fayette County Prosecutor Jess Weade, with regard to the claim for statutory public nuisance in the name of the State of Ohio under R.C. § 3767.03 and R.C. § 4729.35.

2. Defendants

33. Purdue Pharma, L.P. is a limited partnership organized under the laws of Delaware. Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. The Purdue Frederick Company Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. In 2007, Purdue and three of its executives pleaded guilty to federal criminal charges for deceptively marketing opioids.

34. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid and Dilaudid-HP, Butrans, and Hysingla ER in the United States and in

Fayette County.[9] OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2 and $3 billion. Nationwide, OxyContin constitutes roughly 25% of the entire market, by spending, for prescription opioids.

35. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA acquired Cephalon, Inc. in October 2011. Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva USA and Cephalon work together closely to market and sell Cephalon products in the United States and Ohio. Teva USA also sells generic opioids across the Country, including generic opioids previously sold by Allergan plc, whose generics business Teva Pharmaceutical Industries Ltd., Teva USA's parent company based in Israel, acquired in August 2016.

36. Teva manufactures, promotes, sells, and distributes opioids such as Actiq, a fentanyl lollipop, and Fentora, a dissolving pill across the Country. Actiq and Fentora have been approved by the U.S. Food and Drug Administration ("FDA") only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

37. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New

[9] Purdue also obtained approval to market Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride) in 2014, but it has not actively marketed it.

Jersey. Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. These parties are collectively referred to as "Janssen."

38. Janssen manufactures, promotes, sells, and distributes drugs across the U.S., including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

39. J&J imposes a "code of conduct" on Janssen as a pharmaceutical subsidiary of J&J. Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. Janssen's website "Ethical Code for the Conduct of Research and Development," names only J&J and does not mention Janssen anywhere within the document. The "Ethical Code for the Conduct of Research and Development" posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

40. Similarly, the "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "Pharmaceutical Companies of J&J" and as one of the "J&J Pharmaceutical Affiliates." It governs how "[a]ll employees of J&J Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise J&J Pharmaceutical Affiliates' products." All

Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case.

41. J&J made payments to thousands of physicians nationwide, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

42. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. These parties are collectively referred to as "Endo."

43. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, across the U.S. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products across the U.S., by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. On July 6, 2017, in response to an FDA request that Endo voluntarily withdraw the product from the market, the company announced that it would stop marketing and selling a reformulated version of Opana ER that it had marketed as abuse-deterrent. *See infra*, Section F.2.

44. Mallinckrodt, plc is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt,

plc describes itself as "a global specialty pharmaceuticals company" that "develops, manufactures, markets and distributes both branded and generic specialty pharmaceutical products and medical imaging agents." Although it has undergone name changes over time, Mallinckrodt, plc has a long history and describes itself as originally founded by Gustavo Mallinckrodt, Otto Mallinckrodt and Edward Mallinckrodt in 1867. Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri. Mallinckrodt Pharmaceuticals has responded to a letter from the FDA concerning Xartemis XR, and the Mallinckrodt Pharmaceuticals logo appears on marketing and/or purportedly educational materials. Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business in St. Louis, Missouri. Mallinckrodt, LLC is licensed to do business in Ohio as both a manufacturer and a wholesaler. Since June 28, 2013, it has been a wholly owned subsidiary of Mallinckrodt, plc. Prior to June 28, 2013 Mallinckrodt, LLC was a wholly-owned subsidiary of Covidien plc. SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri and is a wholly-owned subsidiary of Mallinckrodt plc. Mallinckrodt, plc, Mallinckrodt, LLC, and SpecGx LLC are referred to as "Mallinckrodt."

45. Mallinckrodt manufactures, markets, and sells drugs in the United States including the branded drugs Exalgo and Xartemis XR. Mallinckrodt also has a large generics drug business, including hydrocodone- and oxycodone-combination products, morphine, methadone, hydromorphone, and fentanyl products. In July 2017, Mallinckrodt agreed to pay $35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

46. Cardinal Health, Inc. ("Cardinal") describes itself as a "global, integrated health care services and products company," and is the fifteenth largest company by revenue in the U.S., with annual revenue of $121 billion in 2016. Cardinal distributes pharmaceutical drugs, including opioids, throughout the country. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio. Cardinal has been licensed as a wholesale distributor of dangerous drugs in Ohio since 1990. Based on Defendant Cardinal's own estimates, one of every six pharmaceutical products dispensed to U.S. patients travels through the Cardinal Health network.

47. McKesson Corporation ("McKesson") is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of $191 billion in 2016. McKesson is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country. McKesson is incorporated in Delaware, with its principal place of business in San Francisco, California. McKesson has been licensed as a wholesale distributor of dangerous drugs in Ohio since 1996. McKesson operates a warehouse in Washington Court House, Ohio.

48. In January 2017, McKesson paid a record $150 million to resolve an investigation by the U.S. Department of Justice ("DOJ") for failing to report suspicious orders of certain drugs, including opioids and for failing to maintain effective controls against diversion at McKesson distribution centers. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Ohio and three other states. The DOJ described these "staged suspensions" as "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."[10]

[10] Department of Justice, "McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs, (Jan. 17, 2017) https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

49. AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of $147 billion in 2016. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania, and it is incorporated in Delaware. AmerisourceBergen has been licensed as a wholesale distributor of dangerous drugs in Ohio since 1988. AmerisourceBergen operates a warehouse in Lockbourne, Ohio. A division of AmerisourceBergen, Besse Medical Services, Inc., operates a warehouse in West Chester, Ohio.

50. Walgreens Boots Alliance d/b/a Walgreen Co ("Walgreens") is a Delaware corporation with its headquarters in Deerfield, Illinois. Walgreens for years included a captive distributor that supplied pharmaceutical drugs and opioids to Walgreens pharmacies in Fayette County and throughout the country. Walgreens also operates pharmacy locations dispensing prescriptions, including opioids, in the County. Nationwide, Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than $118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal year 2017.

51. Upon information and belief, Walgreens has traditionally served as a distributor of generic pharmaceutical products, like generic oxycodone and hydrocodone, to its own stand-alone pharmacy locations, known as "Well Experience" locations. Walgreens also contracted with outside pharmaceutical wholesale distributors, including upon information and belief, Cardinal and AmerisourceBergen, to distribute branded pharmaceutical products, including opioids, to Well Experience locations.

52. Walgreens represented 30% of AmerisourceBergen's revenue in and was its largest customer in 2017. As a part of the agreement, Walgreens gained purchase rights to AmerisourceBergen equity, allowing it to further participate in the prescription drug shipment boom in America. Walgreens subsequently exercised these purchase rights, ultimately owning approximately 26% of AmerisourceBergen.

53. This equity ownership in AmerisourceBergen provided Walgreens even more information about the rampant problem of suspicious opioid shipments in the County. As part of the transaction, Walgreens has the ability to nominate up to two members of the Board of Directors of AmerisourceBergen. Currently, Walgreen's Co-Chief Operating Officer, who oversees Walgreens' business operation, including distribution, sits on the AmerisourceBergen Board of Directors.

54. Defendant CVS Health Corporation ("CVS Health") is a Delaware corporation with its principal place of business in Rhode Island. CVS has a vertically integrated business model, operating as both a wholesale distributor of prescription opioids to pharmacy customers and its own pharmacy stores and pharmacy locations dispensing opioids. CVS, through its various DEA registrant subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. CVS Health describes itself as "a pharmacy innovation company helping people on their path to better health, including "[t]hrough its 9,700 retail locations, more than 1,100 walk-in medical clinics, a leading pharmacy benefits manager with nearly 90 million plan members, a dedicated senior pharmacy care business serving more than one million patients per year," among other services. CVS Health touts what it describes as its "unique integrated model" as "increas[ing] access to quality care, deliver[ing] better health outcomes and lower[ing] overall health care costs." Defendant CVS Indiana, LLC is an Indiana limited liability company with its principal place of

business in Indianapolis, Indiana. Defendant CVS Pharmacy, Inc. is a Rhode Island corporation with its principal place of business in Rhode Island, and is registered to do business in Ohio. Defendant Ohio CVS Stores, LLC is an Ohio corporation registered to do business in Ohio. Defendants CVS Health Corporation, CVS Indiana, LLC are collectively referred to as "CVS."

55. At all times relevant to this Complaint, CVS distributed prescription opioids throughout the United States, including in Ohio. CVS also has a numerous pharmacies stores in Ohio, including pharmacies in the County.

56. Defendants include the above-referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the marketing, distribution, sale and/or dispensing of opioids.

57. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

58. For Defendant Jane Does 1 – 50, the County lacks sufficient information to specifically identify the true names or capacities, whether individual, corporate, or otherwise, of these Defendants. The County will amend this Complaint to show their true names when they are ascertained.

JURISDICTION AND VENUE

59. This Court has jurisdiction over this matter pursuant to R.C. § 2305.01.

60. No federal court has jurisdiction over this action, which asserts exclusively state law claims.

61. This Court has personal jurisdiction over all Defendants under R.C. § 2307.382 because the causes of action alleged in this Complaint arise out of each Defendants' transacting business in Ohio, contracting to supply services or goods in this state, causing tortious injury by an act or omission in this state, causing tortious injury in Ohio and because the Defendants regularly do or solicit business or engage in a persistent course of conduct or deriving substantial revenue from goods used or consumed or services rendered in this state. Defendants have purposefully directed their actions towards Ohio and/or have the requisite minimum contacts with Ohio to satisfy any statutory or constitutional requirements for personal jurisdiction.

62. The damages sought in this action exceed the amount of the exclusive original jurisdiction of the municipal courts.

63. The venue for this claim is proper in the Court of Common Pleas of Fayette County under Ohio Civ. R. 3(B)(3), (6), and (7).

A. ADDITIONAL ALLEGATIONS COMMON TO ALL COUNTS

64. Until the mid-1990s, opioids were widely thought to be too addictive for use for chronic pain conditions, which would require long-term use of the drugs at increasingly high doses. For these conditions, the risks of addiction and other side effects outweighed any benefit from the drugs. Over the last two decades, Marketing Defendants turned that consensus on its head by falsely denying the risk of addiction and overstating the benefits of using opioids long-term.

65. Through marketing that was as pervasive as it was deceptive, these Defendants convinced health care providers both that the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven.

66. The result was that by the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions. Marketing Defendants not only marketed opioids for chronic pain

conditions but also targeted primary care physicians (along with nurse practitioners and physician assistants), who were most likely to see patients with chronic pain conditions and least likely to have the training and experience to evaluate these Defendants' marketing claims.

67. Marketing Defendants' deceptive marketing created a cadre of doctors who looked for pain and treated it with opioids, which created an even broader cohort of patients who expected and received opioids. This laid the groundwork for today's epidemic of opioid addiction, injury, and death.

B. MARKETING DEFENDANTS FALSELY TRIVIALIZED, MISCHARACTERIZED, AND FAILED TO DISCLOSE THE KNOWN, SERIOUS RISK OF ADDICTION.

68. Marketing Defendants spent hundreds of millions of dollars on promotional activities and materials, including advertising, websites, and in-person sales calls, that falsely denied or trivialized the risk of addiction and overstated the benefits of opioids. They also relied upon unsupported and misleading information derived from seminars, treatment guidelines, and other publications and programs by patient advocacy groups, professional associations, and physicians that seemed independent and therefore credible, but were actually funded and controlled by Marketing Defendants.

69. Marketing Defendants also rely on their sales representatives to convey their marketing messages and materials to prescribers in targeted, in-person settings. To ensure that sales representatives deliver the desired messages to prescribers, Marketing Defendants direct and monitor their sales representatives through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' notes (known as "call notes") from each visit. Marketing Defendants likewise required their sales representatives to use sales aids reviewed, approved, and supplied by the companies. They further ensured marketing consistency nationwide through national and regional sales representative training. For example, Purdue provided multi-

week trainings for sales representatives at its headquarters in Connecticut, followed by field training in the target area with more seasoned representatives. Thus, the companies' sales forces in Fayette County, upon information and belief, carried out national marketing strategies, delivering centrally scripted messages and materials that were consistent across the country. Public information discloses that sales representatives from Purdue visited doctors in the County, and these visits, which are recorded only when a payment is made, likely underrepresent the sales calls made in the County.

70. In addition, Purdue recruited and paid respected health care professionals as "speakers" who presented Purdue-approved programs to other prescribers at lunch and dinner events. From 1996 to 2001, Purdue held more than 40 national conferences and more than 5,000 physicians, pharmacist, and nurses attended these speaker conferences. In addition to speaker programs, Purdue targeted doctors with "educational" programming and funded more than 20,000 pain-related educational programs through direct sponsorship or financial grants by July 2002.

71. Purdue was not alone in using this tactic. Marketing Defendants cooperated in using "key opinion leaders" ("KOLs")—experts in the field who were especially influential because of their reputations and seeming objectivity—to deliver paid talks and continuing medical education programs (or "CMEs") that provided information about treating pain and the risks, benefits, and use of opioids. These KOLs received substantial funding and research grants from these Defendants, and the CMEs were often sponsored by Defendants—giving them considerable influence over the messenger, the message, and the distribution of the program. Only doctors supportive of the use and safety of opioids for chronic pain received these funding and speaking opportunities, which were not only lucrative, but also helped doctors build their reputations and

bodies of work. One notable KOL, Dr. Russell Portenoy, subsequently acknowledged that he gave lectures on opioids that reflected "misinformation" and were "clearly the wrong thing to do."

72. In addition to talks and CMEs, these KOLs served on the boards of patient advocacy groups and professional associations, such as the American Pain Foundation and the American Pain Society, that were also able to exert greater influence because of their seeming independence. Defendants exerted influence over these groups by providing major funding directly to them, as well. These "front groups" for the opioid industry put outpatient education materials and treatment guidelines that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks. In many instances, Marketing Defendants distributed these publications to prescribers or posted them on their websites.

73. The FDA does not regulate all of the conduct in which Marketing Defendants engaged. For example, drug labels do not address the use of opioids in treating specific conditions such as lower back pain, headaches, or fibromyalgia, three conditions for which opioids are ineffective, but for which Purdue and, upon information and belief, the other Marketing Defendants, marketed their drugs. The FDA also does not regulate unbranded advertising. Likewise, the FDA does not regulate marketing funneled through third-parties.

74. Neither the third-party, unbranded materials, nor the marketing messages or scripts relied on by Marketing Defendants' sales representatives, were reviewed or approved by the FDA. Upon information and belief, all of the messages described below were disseminated to Fayette County prescribers and patients through sales representative visits, medical education programs, marketing materials, websites, or other sources.

1. Minimizing or mischaracterizing the risk of addiction

75. To convince prescribers and patients that opioids are safe, Marketing Defendants deceptively represented that the risk of abuse and addiction is modest and manageable and limited

to illegitimate patients, not those with genuine pain. This created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted, (2) patients at greatest risk of addiction could be identified, and (3) all other patients could safely be prescribed opioids.

76. Upon information and belief,[11] Marketing Defendants also undermined evidence that opioids are addictive by omitting discussion of addiction, or by promoting a particular drug as less likely to be abused.

77. Marketing Defendants also failed to disclose to prescribers, including, upon information and belief, in Fayette County the difficulty of withdrawing from opioids. For example, a 2011 non-credit educational program sponsored by Endo, entitled Persistent Pain in the Older Adult, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient's opioid dose over ten days. However, this claim is at odds with the experience of patients addicted to opioids. Most patients who are dependent upon or addicted to opioids will experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. This painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

78. For example, Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management,* which taught that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but did not

[11] Unless otherwise noted, allegations based on "information and belief" are based on the uniformity of Defendants' nationwide strategy and practices, which would reasonably be expected to apply in Fayette County in the same manner as elsewhere.

disclose the significant hardships that often accompany cessation of use, even when gradually tapering off.

79. A 2010 Purdue "Training Guide for Healthcare Providers" on OxyContin claimed that patients who were physically dependent on opioids, but who had not developed an "addiction disorder" "[c]an generally discontinue their medicine with mild to no withdrawal syndrome once their symptoms are gone by gradually tapering the dosage according to their doctor's orders."

80. Marketing Defendants falsely portrayed "true" addiction in its narrowest form. For example, *Providing Relief, Preventing Abuse*, a pamphlet published by Purdue in 2011 for prescribers and law enforcement, shows pictures of the signs of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa—under the heading "Indications of Possible Drug Abuse." These depictions misleadingly reassured doctors that, in the absence of those extreme signs, they need not worry that their patients are abusing or addicted to opioids. But Purdue knew that individuals who resort to these extremes are uncommon; they far more typically become dependent and addicted through oral use. According to briefing materials Purdue submitted to the FDA in October 2010, OxyContin was used non-medically by injection as little as 4% of the time. Purdue made *Providing Relief, Preventing Abuse* available to sales representatives to show to or leave with prescribers, including, on information and belief, prescribers in Fayette County.

81. Purdue also disseminated misleading information about opioids and addiction through the American Pain Foundation ("APF"), over which Purdue and other Defendants exercised control.[12] For example, *A Policymaker's Guide to Understanding Pain & Its*

[12] In practice, APF operated in close collaboration with opioid makers. On several occasions, representatives of the drug companies, often at informal meetings, suggested activities

Management, a 2011 APF publication that Purdue sponsored, claimed that pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction." This guide also asserted, without basis, that "less than 1% of children treated with opioids become addicted" and perpetuated the concept of pseudoaddiction (*see* Section A.2, *infra*). Purdue provided substantial funding to APF and closely collaborated with APF in creating *A Policymaker's Guide.* On information and belief, based on Purdue's close relationship with APF and the periodic reports APF provided to Purdue about the project, Purdue had editorial input into *A Policymaker's Guide*. It is still available to Fayette County prescribers online.

82. Purdue also maintained a website from 2008 to 2015, *In the Face of Pain*, that downplayed the risks of chronic opioid therapy. Purdue deactivated this website in October 2015 following an investigation by the New York Attorney General. *In the Face of Pain* asserted that policies limiting access to opioids are "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors who will treat their pain. While a document linked from the website briefly mentioned opioid abuse, the site itself *never* mentioned the risk of addiction. At the same time, the website contained testimonials from several dozen physician

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and publications for APF to pursue, which they then funded APF to pursue. Purdue was APF's second-biggest donor. The largest donor, from 2007 until APF closed its doors in 2012, was Endo, which provided more than half of APF's $10 million in total funding during that time period. Purdue grant letters informed APF that Purdue's contributions reflected the company's effort to "strategically align its investments in nonprofit organizations that share [its] business interests." Purdue also engaged APF as a paid consultant on various initiatives and deployed APF to lobby for its interests on Capitol Hill, for example, by opposing legislation that would have restricted the use of long-acting (but not short-acting) opioids, which would distinctly disadvantage Purdue.

The close relationship between APF and Purdue was not unique, but mirrors relationships between APF and Defendants. APF's clear lack of independence—in its finances, management, and mission—and its willingness to allow Defendants to control its activities and messages support an inference that each Defendant that worked with it was able to exercise editorial control over its publications.

"advocates" speaking positively about opioids. Eleven of these advocates received a total of $231,000 in payments from Purdue from 2008 to 2013—a fact notably omitted from the site.

83. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

84. Endo also distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website, www.opana.com.

85. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain."

86. Janssen currently runs a website, *Prescriberesponsibly.com*, which claims that concerns about opioid addiction are "overestimated."

87. Mallinckrodt also provided funding to organizations in order to disseminate false messages about opioids. Until at least June 2007, Mallinckrodt gave education grants to pain-topics.org, a now-defunct website that proclaimed to be an organization "dedicated to offering contents that are evidence-based, unbiased, non-commercial, and comply with the highest standards and principles of accrediting and other oversight organizations."

88. Among its content, the website contained a handout titled *Oxycodone Safety for Patients*, released in June 2007, which advised doctors that "[p]atients' fears of opioid addiction

should be dispelled."[13] The handout misleadingly stated that "[a]ddiction to oxycodone in persons without a recent history of alcohol or drug problems is rare." It also misleadingly characterized withdrawal symptoms as occurring only if medication is suddenly stopped and suggested that gradually lowering the dose as a way to "help prevent" withdrawal symptoms, which the handout characterized mildly as merely "uncomfortable" symptoms that may include "diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings." This handout is still available to prescribers and patients today.

89. Purdue and Endo also sponsored APF's *Exit Wounds* (2009), which targeted veterans and misleadingly portrayed addiction as resulting only from recreational use or other intentional abuse of opioids and misleadingly suggested that patients using the drugs as prescribed would not become addicted, or even experience withdrawal symptoms upon discontinuing the drugs, unless their dosage were stopped or lowered too abruptly:

> Physical dependence means that a person will develop symptoms and signs of withdrawal (e.g., sweating, rapid heart rate, nausea, diarrhea, goosebumps, or anxiety) if a drug medication is suddenly stopped or the dose is lowered too quickly. . . . Physical dependence is normal. This does not mean you are addicted. Opioid medications can, however, be abused or used as recreational drugs, and some people who use drugs in this way *will* become addicted. Addiction is a disease state in which people can no longer control their use of a drug that is causing them harm.

90. Mallinckrodt in 2010 created the C.A.R.E.S. (Collaborating and Acting Responsibly to Ensure Safety) Alliance, which it describes as "a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits." Mallinckrodt describes C.A.R.E.S as its own advocacy program, and promised "[t]hrough the C.A.R.E.S. Alliance

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[13] Lee A. Kral, *Commonsense Oxycodone Prescribing & Safety*, http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf.

website, prescribers and pharmacists can access tools and resources to assist them in managing the risks of opioid pain medications, and patients can find information designed to help them better manage their pain and understand the responsible use of the medications they take."

91. The C.A.R.E.S. Alliance publicly describes itself as "[c]reated with leading pain experts through a scientific process" and offering "free resources" to "promote safe prescribing, dispensing, use, storage, and disposal" of opioid pain medications. It further described the "safe-use programs and voluntary tools" it developed as "grounded in science and research." The "C.A.R.E.S. Alliance" itself is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.) copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

92. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled *Defeat Chronic Pain Now!*. This book is still available online in Fayette County and elsewhere. The false claims and misrepresentations in this book include the following statements:

- "Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- "[O]pioid medication may also significantly relieve many patients' chronic pain. Over the past decade, lots of good scientific studies have shown that long-acting opioids can reduce the pain in some patients with low back pain, neuropathic pain, and arthritis pain."
- "It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy."
- "[P]hysical dependence . . . is a normal bodily reaction that happens with lots of different types of medications, including medications not used for pain, and is easily remedied."
- "When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving."

- "[I]n our experience, the issue of tolerance is overblown."
- "Only a minority of chronic pain patients who are taking long-term opioids develop tolerance."
- "**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction."
- "Here are the facts. It is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."
- "Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction."

93. Mallinckrodt's former parent Company, Covidien, published a patient resource, "Opioid Safe Use and Handling Guide," which stated that: "Addiction does not often develop when taking opioid pain medicine as prescribed under the guidance of a health care provider, but it can occur;" and "Taking more than your prescribed amount of medication to treat your pain is not the same as addiction, but it can be very dangerous."

94. Marketing Defendants' efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. Studies have shown that at least 8-12%, and as many as 30-40% of long-term users of opioids experience problems with addiction. Addiction can result from the use of any opioid, "even at recommended dose"[14] and the risk increases with chronic (more than three months) use.

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[14] *FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics,* FDA (Sept. 10, 2013); *see also FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death,* FDA (Mar. 22, 2016), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

2. Marketing Defendants Falsely Described Addiction as Pseudoaddiction and Dangerously Encouraged Doctors to Respond by Prescribing More Opioids.

95. Marketing Defendants covered up the occurrence of addiction by attributing it to a made-up condition they called "pseudoaddiction." This concept taught that signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids or seeking early refills, actually reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel.

96. For example, a 2010 Purdue "Training Guide for Healthcare Providers" on OxyContin taught that "[b]ehaviors that suggest drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior."

97. Purdue also disseminated the Definitions Related to the Use of Opioids for the Treatment of Pain section of a "consensus statement" published by the American Pain Society ("APS"), which Purdue heavily funded. Purdue disseminated this definition though Purdue's unbranded *Partners Against Pain* website.[15] APS defined pseudoaddiction in the same terms endorsed by Purdue:

> Physical dependence, tolerance, and addiction are discrete and different phenomena that are often confused.... Pseudoaddiction is a term which has been used to describe patient behaviors that may occur when pain is undertreated. Patients with unrelieved pain may become focused on obtaining medications, may "clock watch," and may otherwise seem inappropriately "drug seeking." Even such behaviors as illicit drug use and deception can occur in the patient's efforts to obtain relief. Pseudoaddiction can be distinguished from true addiction in that the behaviors resolve when pain is effectively treated. Physical dependence on and tolerance to prescribed drugs do not constitute sufficient evidence of psychoactive

[15] *Partners Against Pain* consists of both a website, styled as an "advocacy community" for better pain care, and medical education resources distributed to prescribers by the sales force. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin's addictiveness by claiming: "Drug addiction means using a drug to get 'high' rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful."

> substance use disorder or addiction. They are normal responses that often occur with the persistent use of certain medications....A patient who is physically dependent on opioids may sometimes continue to use these despite resolution of pain only to avoid withdrawal. Such use does not necessarily reflect addiction.

98. Purdue, through its unbranded imprint *Partners Against Pain*, promoted the concept of pseudoaddiction through at least 2013 on its website.

99. Purdue directly disseminated materials about "pseudoaddiction" through a brochure entitled *Providing Relief, Preventing Abuse*. The 2008 edition of *Providing Relief, Preventing Abuse* explained that the term "pseudoaddicton"

> describes the misinterpretation by members of the health care team of relief-seeking behaviors in a person whose pain is inadequately treated as though they were drug-seeking behaviors as would be common in the setting of abuse. The lack of appropriate response to the behaviors can result in an escalation of them by the patient, in an attempt to get adequate analgesia.

100. The 2008 edition of *Providing Relief, Preventing Abuse* further explained that "[p]seudoaddiction can be distinguished from addiction in that the behaviors resolve when pain is effectively treated."

101. By 2011, Purdue had revised the brochure, and the second edition of *Providing Relief, Preventing Abuse* explained that:

> Some patients may exhibit behaviors aimed at obtaining pain medication because their pain treatment is inadequate. The term *pseudoaddiction* has emerged in the literature to describe the inaccurate interpretation of these behaviors in patients who have pain that has not been effectively treated. Pseudoaddiction behaviors can be distinguished from addiction by the fact that, when adequate analgesia is achieved, the patient who is seeking pain relief demonstrates improved function, uses the medications as prescribed, and does not use drugs in a manner that persistently causes sedation or euphoria.

102. The 2014 edition of *Providing Relief, Preventing Abuse* dropped the term "pseudoaddiction" but included an "Other Considerations" section that stated that "[s]ome patients

may exhibit behaviors aimed at obtaining pain medication because their pain treatment is inadequate. Such behaviors may occur occasionally even with successful opioid therapy for pain; a pattern of persistent occurrences should prompt concern and further assessment."

103. The Federation of State Medical Boards ("FSMB"), a trade organization representing the State Medical Board of Ohio as well as others, finances opioid- and pain-specific programs through grants from Defendants. A 2004 version of the FSMB *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), and the 2007 book adapted from them, *Responsible Opioid Prescribing*, advanced the concept of pseudoaddiction.

104. *Responsible Opioid Prescribing* was sponsored by Purdue, Endo, and Teva. The FSMB website described the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications." In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally, including, upon information and belief, in Ohio.

105. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when *pain is under-treated* . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until May 2012.

106. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC, an initiative run by the APF, by funding NIPC projects; developing, specifying, and reviewing its content; and distributing NIPC materials. APF internal documents show that APF viewed the NIPC as an "opportunity to generate new revenue" given Endo's funding commitment.

107. Marketing Defendants also promoted the concept of pseudoaddiction through Dr. Russell Portenoy, a leading KOL for the Defendants. In doing so, he popularized the concept and falsely claimed that pseudoaddiction is substantiated by scientific evidence.

108. The FAQs section of pain-topics.org, a now-defunct website to which Mallinckrodt provided funding, also contained misleading information about pseudoaddiction. Specifically, the website advised providers to "keep in mind" that signs of potential drug diversion, rather than signaling "actual" addiction, "may represent pseudoaddiction," which the website described as behavior that occurs in patients when pain is "undertreated" and includes patients becoming "very focused on obtaining opioid medications and may be erroneously perceived as 'drug seeking.'"

109. The CDC Guideline for prescribing opioids for chronic pain, a "systematic review of the best available evidence" by a panel excluding experts without conflicts of interest, rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid doses be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,"[16] and that physicians should "reassess pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[17]

3. Overstating the efficacy of screening tools.

110. Marketing Defendants falsely instructed prescribers and patients that screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to

[16] CDC Guideline at 13.

[17] *Id.* at 25.

safely prescribe opioids to patients, including patients predisposed to addiction, and failed to disclose the lack of evidence that these strategies actually work to mitigate addiction risk. By using screening tools, Marketing Defendants advised doctors that they could identify patients likely to become addicted and safely prescribe to everyone else.

111. Such misrepresentations regarding safe opioid prescribing made health care providers more comfortable prescribing opioids to their patients and patients more comfortable starting chronic opioid therapy. These misrepresentations were especially insidious because Marketing Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Moreover, these misrepresentations allowed doctors to believe opioid addiction was the result of other prescribers failing to rigorously manage and weed out problem patients, not a risk inherent to the drugs.

112. Marketing Defendants conveyed these safe prescribing messages through their in-person sales calls to doctors, including, upon information and belief, in the County based on the uniformity of their nationwide marketing strategy and training of sales representatives

113. Marketing Defendants also promoted screening tools as a reliable means to manage addiction risk in CME programs and scientific conferences, which would have been attended by and were available online, to Fayette County prescribers.

114. For example, Purdue sponsored a 2011 CME program titled Managing Patient's Opioid Use: Balancing the Need and Risk. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths." Purdue also funded a 2012 CME program called Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes. The presentation

deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addiction could be treated with opioids.

115. Purdue used its involvement in the College on the Problems of Drug Dependence ("CPDD"), which promotes scientific research and professional development to support addiction prevention professionals, to promote the idea that addiction risk can be managed. A Purdue employee served on the CPDD board of directors. Purdue presented a disproportionate number of talks—with very different messages from non-Purdue talks—at CPDD conferences. One of Purdue's consistent themes is that "bad apple" patients, not opioids, are the source of the opioid crisis, and that once those patients are identified doctors can safely prescribe opioids without a risk of addiction. Hundreds of addiction treatment specialists from across the country and, upon information and belief, prescribers from Fayette County, attended these conferences.

116. Endo paid for a 2007 supplement in the Journal of Family Practice written by a doctor who became a member of Endo's speakers bureau (doctors paid to give talks, typically reserved for the largest prescribers) in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

117. The CDC Guideline confirmed the falsity of Marketing Defendants' claims about the utility of patient screening and management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools or patient contracts—"for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognized that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse

or misuse" and counseled that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[18]

C. MARKETING DEFENDANTS OVERSTATED THE BENEFITS OF CHRONIC OPIOID THERAPY WHILE FAILING TO DISCLOSE THE LACK OF EVIDENCE SUPPORTING LONG-TERM USE.

1. Mischaracterizing the benefits of and evidence for long-term use.

118. To convince prescribers and patients that opioids should be used to treat chronic pain, Marketing Defendants had to persuade them of a significant upside to long-term opioid use. Assessing existing evidence, the CDC Guideline found that there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain."[19] In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials $\leq$ 6 weeks in duration)"[20] and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."[21] As a result, the CDC recommends that opioids not be used in the first instance for treatment of chronic pain; rather, opioids should be used only after prescribers have exhausted alternative treatments. Likewise, the Ohio Guidelines for Prescribing Opioids for the Treatment of Chronic Non-Terminal Pain 80 mg

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[18] CDC Guideline at 28 (emphasis added).

[19] *Id.* at 10.

[20] *Id.* at 9.

[21] Letter from Janet Woodcock, M.D, Dir., Center for Drug Eval. and Research, to Andrew Kolodny, M.D. (Sept. 10, 2013).

of a Morphine Equivalent Daily Dose (MED) "Trigger Point," released in October 2013, call for providers to consider non-opioid therapies first.[22]

119. That has not changed. Indeed, a recent study found that "the use of opioid vs nonopioid medication therapy did not result in significantly better pain-related function over 12 months." These results did "not support initiation of opioid therapy for moderate to severe chronic back pain or hip or knee osteoarthritis pain."[23]

120. Nevertheless, Marketing Defendants touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence.

121. In addition, two prominent professional medical membership organizations, the APS and the American Academy of Pain Medicine ("AAPM"), each received substantial funding from Defendants. Upon information and belief, Defendants exercised considerable influence over their work on opioids. Both organizations issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was at the time a paid speaker for Purdue and later became a senior executive for the company. KOL Dr. Portenoy was the sole consultant. The consensus

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[22] http://mha.ohio.gov/Portals/0/assets/Initiatives/GCOAT/Guidelines-Chronic-Pain.pdf

[23] Krebs EE, Gravely A, Nugent S, et al. Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain: The SPACE Randomized Clinical Trial. *JAMA.* 2018;319(9):872–882. doi:10.1001/jama.2018.0899, *available at* https://jamanetwork.com/journals/jama/article-abstract/2673971?redirect=true

statement remained on AAPM's website until 2011 and was only removed from AAPM's website after a doctor complained.

122. A past president of the AAPM, Dr. Scott Fishman, who also served as a KOL for Defendants, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[24]

123. AAPM and APS issued treatment guidelines in 2009 ("AAPM/APS Guidelines") which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines, like the AAPM/APS Guidelines, were particularly important to Marketing Defendants in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. Six of the twenty-one panel members who drafted the AAPM/APS Guidelines received support from Purdue, eight from Teva, nine from Janssen, and ten from Endo.

124. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendations" despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

[24] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), available at http://www.medscape.org/viewarticle/500829.

125. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including the high presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

126. The AAPM/APS Guidelines are still available online, were reprinted in the *Journal of Pain*, and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited at least 1,833 times in academic literature.

127. Purdue, for example, also published misleading studies to enhance the perception that opioids are effective long-term for chronic pain conditions. One study asserts that OxyContin is safe and effective for the chronic pain condition osteoarthritis. The study, sponsored by Purdue, involved providing oxycodone for 30 days, and then randomizing participants and providing a placebo, an immediate release oxycodone with acetaminophen (like Percocet), or OxyContin. Only 107 of the 167 patients went on to the second phase of the study, and most who withdrew left because of adverse events (nausea, vomiting, drowsiness, dizziness, or headache) or ineffective treatment. Despite relating to a chronic condition, opioids were provided only short-term. The authors even acknowledge that the "results . . . should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition such as OA [osteoarthritis]."[25] Yet, the authors conclude that "[t]his clinical experience shows that opioids were well tolerated with only rare

[25] Jacques R. Caldwell, *et al.*, *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial*, 266.4 Journal of Rheumatology 862-869 (1999).

incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids long-term."[26] This statement is not supported by the data—a substantial proportion of patients dropped out because of adverse effects, there was no reported data regarding addiction, and the study was not long-term.

128. Teva deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals.

129. Both Actiq and Fentora are extremely powerful fentanyl-based opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Teva from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risks of "serious and life-threatening adverse events" and abuse—which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

130. Despite this, Teva has conducted a well-funded and deceptive campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Teva used CMEs, speaker programs, KOLs, journal supplements, and "detailing" visits by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain, without disclosing the lack of evidence or the FDA's rejection of their use for chronic pain.

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[26] *Id.*

131. For example, Teva paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

132. Teva's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

133. In December 2011, Teva widely disseminated a journal supplement entitled *"Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)"* to Anesthesiology News, Clinical Oncology News, and Pain Medicine News—three publications that are sent to thousands of anesthesiologists and other medical professionals nationally, including, upon information and belief, in Fayette County. The Special Report openly promotes Fentora for "multiple causes of pain," and not just cancer pain.

134. Teva's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but also were approved by the FDA for such uses.

135. On December 28, 2011, the FDA mandated a Risk Evaluation and Mitigation Strategy (REMS) for the class of products for which Teva's Actiq and Fentora belong, Transmucosal Immediate Release Fentanyl (TIRF). The TIRF REMS programs include mandatory patient and prescriber enrollment forms, as well as certification requirements for prescribers. The forms are not comprehensive and do not, for instance, disclose that addiction can

develop when prescribed as directed, nor do they disclose that risks are greatest at higher doses—and patients must already be taking high doses of opioids to be prescribed Actiq and Fentora.

2. Overstating opioids' effect on patients' function and quality of life

136. Upon information and belief, Marketing Defendants also claimed—without evidence—that long-term opioid use would help patients resume their lives and jobs.

137. Marketing Defendants' materials that, upon information and belief, were distributed or made available in Fayette County reinforced this message. The 2011 publication *A Policymaker's Guide* falsely claimed that "multiple clinical studies have shown that opioids are effective in improving" "[d]aily function" and "[o]verall health-related quality of life for people with chronic pain." A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively. Similarly, since at least May of 2011, Endo has distributed and made available on its website, opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement.

138. Additional illustrative examples are described below:

a. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as "a fact" that "opioids may make it *easier* for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

b. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Teva, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

c. Purdue and Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in May 2012.

d. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make claims of functional improvement, and Endo closely tracked visits to the site.

e. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

139. Mallinckrodt followed suit, stating on its website, in a section on "responsible use" of opioids, claims that "[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society."

140. Marketing Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. As noted above, there are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long-term. On the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients' health and pain. Increasing the duration of opioid use is strongly associated with an increased prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

141. As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[27] Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures.

142. Yet, Marketing Defendants targeted these patients. For example, a former sales representative has explained that he was directed to market Purdue's OxyContin for chronic pain, including lower back pain and pain from arthritis, and to focus prescribers on patients with pain that prevented them from working or functioning day to day.

143. The FDA and other federal agencies have, for years, made clear the lack of evidence for claims that the use of opioids for chronic pain improves patients' function and quality of life.[28] The CDC Guideline, following a "systematic review of the best available evidence," concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for

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[27] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), available at http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse?

[28] The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Defendants on the FDA website.

chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[29] According to the CDC director, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[30] The Ohio Guidelines for Prescribing Opioids for the Treatment of Chronic, Non-Terminal Pain 80 mg of a Morphine Equivalent Daily Dose (MED) "Trigger Point" similarly state that "[p]roviders should avoid starting a patient on long-term opioid therapy when treating chronic pain."

144. Similarly, analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000.00, stemming from greater side effects and slower returns to work. According to these studies, receiving an opioid for more than seven days also increased patients' risk of being on work disability one year later.

3. Omitting or mischaracterizing adverse effects of opioids.

145. In materials Marketing Defendants produced, sponsored, or controlled, these Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or nonsteroidal anti-inflammatory drugs (or NSAIDs, like ibuprofen). None of these claims were corroborated by scientific evidence.

146. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and death, Defendants routinely ignored other risks, such as hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy,"[31] in which the patient

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[29] CDC Guideline at 2, 18.

[30] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1503 (Apr. 21, 2016).

[31] *See* n.40, *supra*.

becomes more sensitive to pain over time; hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (conditions that often accompany chronic pain symptoms).

147. Purdue and Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication inaccurately attributes 10,000 to 20,000 deaths annually to NSAIDs (the actual figure is approximately 3,200—far fewer than from opioids).[32] This publication also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

148. Purdue and Endo also sponsored APF's *Exit Wounds* (2009), a book aimed at veterans. This book omits warnings of the potentially fatal risk of interactions between opioids and benzodiazepines, a class of drug commonly prescribed to veterans with post-traumatic stress disorder. This book is available from Amazon.com and other retailers.

149. Purdue and Endo sponsored a CME program, *Overview of Management Options*, published by the American Medical Association in 2003, 2007, 2010, and 2013, and discussed further below. The CME was edited by Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

[32] The higher figure reflects deaths from all causes.

150. Marketing Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of NSAIDs. These Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. (*See e.g.*, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) [describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids]; *Finding Relief: Pain Management for Older Adults* (Janssen) [NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause temporary "upset stomach or sleepiness" and constipation].)

151. These omissions are significant and material to patients and prescribers. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found that 22.9% of patients in opioid trials dropped out before the study began because of the "intolerable effects" of opioids.[33]

152. Again, Marketing Defendants' misrepresentations were effective. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions fell from 38% to 29%. Another study of an estimated 440 million visits for back pain over a period from 1999 to 2010 found that use of NSAIDs fell from 36.9% to 24.5%, while use of narcotics increased from 19.3% to 29.1.%. The CDC reports that the quantity of opioids dispensed per capita tripled from 1999 to 2015.

[33] Meredith Noble M, *et al.*, *Long- Term Opioid Management for Chronic Noncancer Pain (Review)*, Cochrane Database of Systematic Reviews, Issue 1, 11 (2010).

D. MARKETING DEFENDANTS CONTINUED TO TELL DOCTORS THAT OPIOIDS COULD BE TAKEN IN EVER-HIGHER DOSES WITHOUT DISCLOSING THEIR GREATER RISKS.

153. Marketing Defendants falsely claimed to prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. Defendants needed to generate a comfort level among doctors to ensure the doctors maintained patients on the drugs even at the high doses that became necessary. Further, as described in more detail in Section E, Purdue encouraged doctors to prescribe higher doses, rather than prescribe OxyContin more frequently than twice-a-day—despite knowing that OxyContin frequently did not provide 12 hours of relief.

154. Purdue-sponsored publications and CMEs available online also misleadingly suggested that higher opioid doses carried no added risk.

155. Through at least June 2015, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor did not prescribe a sufficient dose of opioids, the patient should see different doctors until finding a doctor who would.

156. *A Policymaker's Guide,* the 2011 publication on which, upon information and belief, Purdue collaborated with APF, taught that dose escalations are "sometimes necessary," but it did not disclose the risks from high dose opioids. This publication is still available online.

157. The Purdue-sponsored CME, *Overview of Management Options*, discussed above, again instructed physicians that NSAIDs (like ibuprofen) are unsafe at high doses (because of risks to patients' kidneys), but it did not disclose risks from opioids at high doses.

158. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

159. Endo distributed a pamphlet edited by Dr. Russell Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which appeared on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."

160. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

161. These claims conflict with the scientific evidence. Patients receiving high doses of opioids (*e.g.*, doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.

162. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established" while "there is an increased risk for serious harms related to long-term

opioid therapy that appears to be dose-dependent."[34] That is why the CDC advises doctors to "avoid increasing dosages" above 90 mg MED.[35]

E. PURDUE MISLEADINGLY PROMOTED OXYCONTIN AS SUPPLYING 12 HOURS OF PAIN RELIEF WHEN PURDUE KNEW THAT, FOR MANY PATIENTS, IT DID NOT.

163. To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch.

164. OxyContin has been FDA-approved for twice-daily—"Q12"—dosing frequency since its debut in 1996. Purdue sought that dosing frequency in order to maintain a competitive advantage over more frequently dosed opioids. Even so, Purdue has gone well beyond the label's instructions to take OxyContin every 12 hours. Purdue has affirmatively claimed in its general marketing and, upon information and belief, to prescribers in Fayette County, that OxyContin lasts for 12 hours and that this is a key advantage of OxyContin, implying that most or all patients would in fact experience continuous pain relief for the full 12 hour dose period. Purdue has also failed to disclose that OxyContin fails to provide 12 hours of pain relief to many patients. These misrepresentations, which Purdue continues to make, are particularly dangerous because inadequate dosing helps fuel addiction, as explained below.

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[34] CDC Guideline at 19. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

[35] CDC Guideline at 16.

165. From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake to take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as providing "smooth and sustained pain control all day and all night." But the FDA has never approved such a marketing claim. To the contrary, the FDA found in 2008, in response to a Citizen Petition by the Connecticut Attorney General, that a "substantial proportion" of chronic pain patients taking OxyContin experienced "end of dose failure"—*i.e.*, little or no pain relief at the end of the dosing period.

166. Moreover, Purdue itself long has known, dating to its development of OxyContin, that the drug wears off well short of 12 hours in many patients. In one early Purdue clinical trial, a third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental painkillers—"rescue doses"—in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it at least once. In other research conducted by Purdue, the drug wore off in under 6 hours in 25% of patients and in under 10 hours in more than 50%.

167. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin's 12-hour dosing "the perfect recipe for addiction."[36] Many patients will exacerbate

[36] Harriet Ryan, "'*You Want a Description of Hell?' OxyContin's 12-Hour Problem*," Los Angeles Times, May 5, 2016, available at http://www.latimes.com/projects/oxycontin-part1/.

this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

168. Purdue has remained committed to 12-hour dosing because it is key to OxyContin's market dominance and comparatively high price; without this advantage, the drug had little to offer over less expensive, short-acting opioids. In a 2004 letter to the FDA, Purdue acknowledged that it had not pursued approval to allow more frequent dosing in the label (*e.g.,* every 8 hours) because 12-hour dosing was "a significant competitive advantage."

169. While Purdue's commitment to marketing opioids as a 12-hour drug made it more addictive. Upon information and belief, Purdue falsely promoted OxyContin as providing "steady state" relief and less likely than other opioids to create a cycle of crash and cravings that fueled addiction and abuse.

170. Promotion of 12-hour dosing, without disclosing its limitations, is misleading because it implies that the pain relief supplied by each dose lasts 12 hours. FDA approval of OxyContin for 12-hour dosing does not give Purdue license to misrepresent the duration of pain relief it provides to patients; moreover, Purdue had a responsibility to correct its label to reflect appropriate dosing and to disclose to prescribers what it knew about OxyContin's actual duration, but disregarded that responsibility in its pursuit of a marketing advantage.[37]

171. Purdue was also aware of some physicians' practice of prescribing OxyContin more frequently than 12 hours—a common occurrence. Purdue's promoted solution to this problem was either to stop mentioning it, or to increase the dose, rather than the frequency, of prescriptions, even though higher dosing carries its own risks—including increased danger of addiction,

[37] For example, Kadian, an opioid manufactured by Allergan, was designed to be taken once a day, but the label acknowledges and advises dosing of up to every 12 hours for certain patients.

overdose, and death. It means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 MED that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[38]

F. PURDUE AND ENDO OVERSTATED THE EFFICACY OF ABUSE-DETERRENT OPIOID FORMULATIONS, AND MALLINCKRODT ALSO MADE DECEPTIVE CLAIMS.

172. Rather than take the widespread abuse and addiction to opioids as reason to cease their untruthful marketing claims and efforts, Defendants Purdue, Endo, and Mallinckrodt seized them as a market opportunity. These companies oversold their abuse-deterrent formulations ("ADF") as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids. Upon information and belief, their false and misleading marketing of the benefits of ADF opioids preserved and expanded their sales and influenced prescribers to discount evidence of opioid addiction and abuse and attribute it to other, less safe opioids—thereby prolonging the opioid epidemic in Fayette County.

1. Purdue's Deceptive Marketing of Reformulated OxyContin and Hysingla ER.

173. Reformulated ADF OxyContin was approved by the FDA in April 2010. It was not until 2013 that the FDA, in response to a Citizen Petition filed by Purdue, permitted reference to the abuse-deterrent properties in its label. However, the FDA made clear that abuse-deterrent properties do not stop tampering but only make it harder to modify the pills. ADF pills can still be snorted and injected if tampered with, and these pills are still sought after by abusers because of their high likability when snorted. Further, ADF properties do not reduce oral abuse—the most

[38] CDC Guideline at 16.

common form of abuse—in any way. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties and limitations.

174. It is unlikely a coincidence that reformulated OxyContin was introduced shortly before generic versions of OxyContin were to become available, threatening to erode Purdue's market share and the price it could charge. Through a Citizen Petition, Purdue was able to secure a determination by the FDA in April 2013 that original OxyContin should be removed from the market as unsafe (lacking abuse-deterrent properties), and thus non-ADF generic copies could not be sold. As a result, Purdue extended its branded exclusivity for OxyContin until the patent protection on the abuse-deterrent coating expires.

175. Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis. Touting the benefits of ADF opioids, Purdue's website asserts, for instance: "we are acutely aware of the public health risks these powerful medications create . . . That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse . . . ."[39]

176. Ironically, Purdue sales representatives also regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids, including, upon information and belief, in Fayette County. Specifically, Purdue sales representatives:

a. claimed that Purdue's ADF opioids prevent tampering and that its ADFs could not be crushed or snorted;

b. claimed that Purdue's ADF opioids reduce opioid abuse and diversion;

c. asserted or suggested that Purdue's ADF opioids are safer than other opioids; and

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[39] Purdue website, *Opioids With Abuse-Deterrent Properties*, available at http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrentproperties/.

d. failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.

177. These misrepresentations and omissions are misleading and contrary to Purdue's labels.

178. Purdue trained its sales representatives to discuss OxyContin's abuse-deterrent formulation. A former Purdue sales representative in Montana, who had been trained by Purdue, recalled that he often discussed OxyContin's abuse-deterrent formulation with prescribers who were reluctant to prescribe opioids.

179. After Purdue launched reformulated OxyContin, sales increased nationwide.

180. Purdue knew or should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin"[40] and is still regularly tampered with and abused.

181. Websites and message boards used by drug abusers, such as bluelight.org and reddit.com, report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. A publicly available Citizen Petition submitted to the FDA in 2016 by a drug manufacturing firm challenged Purdue's abuse-deterrent labeling based on the firm's ability to easily prepare so-called abuse-deterrent OxyContin to be snorted or injected. Opioid addicts in Fayette County also, upon information and belief, continued to crush, snort, and inject abuse-deterrent formulations of their drugs, including OxyContin and Opana ER.

182. *One-third* of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF

[40] *In re OxyContin*, 1:04-md-01603-SHS, Docket No. 613, Oct. 7, 2013 hr'g, Testimony of Dr. Mohan Rao, 1615:7-10.

opioids was reduced, there was no meaningful reduction in drug abuse, as many addicts simply shifted to other drugs such as heroin.

183. A 2013 article presented by Purdue employees based on review of data from poison control centers, concluded that ADF OxyContin can reduce abuse, but ignored important negative findings. The study revealed that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were *more* harmful exposures to opioids (including heroin) after the reformulation of OxyContin. In short, the article deceptively emphasized the advantages and ignored the disadvantages of ADF OxyContin.

184. The CDC Guideline confirms that "*[n]o* studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[41] Tom Frieden, the Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death."[42]

185. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff was to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated

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[41] CDC Guideline at 22 (emphasis added).

[42] Matthew Perrone, *Drugmakers Push Profitable, but Unproven, Opioid Solution*, Assoc. Press (Jan. 2, 2017), available at https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution

OxyContin product has had a meaningful impact on abuse."[43] Upon information and belief, Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

186. Despite the qualifying language in Purdue's label and its own evidence—and lack of evidence—regarding the impact of its ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers.

2. Endo's Deceptive Marketing of Reformulated Opana ER.

187. In a strategy that closely resembled Purdue's, Endo, as the expiration of its patent exclusivity for Opana ER neared, and aware that it needed to be able to compete with other opioids, like OxyContin, that were being introduced as ADFs, also made abuse-deterrence a key to its marketing strategy.

188. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant. Even prior to its approval, the FDA advised Endo in January 2011 that it could not market new Opana ER as abuse-deterrent. The FDA found that such promotional claims "may provide a false sense of security since the product may be chewed and ground for subsequent abuse."[44] In other words, Opana ER was still crushable. Indeed, in its approval package, Endo admitted that "[i]t has not been

[43] Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

[44] Attorney General of the State of New York, In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc., Assurance No.: 15-2228, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 5.

established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction."

189. Nonetheless, in August of 2012, Endo submitted a confidential Citizen Petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted, and that it was resistant to "aqueous extraction," or injection by syringe. Borrowing a page from Purdue's playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse deterrence). That would prevent generic copies of original Opana ER from competitors, such as Impax Laboratories ("Impax"), which had sought approval to sell a generic version of the drug.

190. Endo then sued the FDA, seeking to force expedited consideration of its Citizen Petition. The court filings confirmed Endo's true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to $135 million per year. Endo also claimed that if the FDA did not block generic competition, $125 million, which Endo spent on developing the reformulated drug to "promote the public welfare" would be lost.[45] The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."[46]

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[45] Plaintiff's Opposition to Defendants' and Intervenor's Motions to Dismiss and Plaintiff's Reply in Support of Motion for Preliminary Injunction ("Endo Br."), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*., No. 1:12-cv-01936, Doc. 23 at 20 (D.D.C. Dec.14, 2012).

[46] Defendants' Response to the Court's November 30, 2012 Order, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*., No. 1:12-cv-01936, Doc. 9 at 6 (D.D.C. Dec. 3, 2012).

191. Despite Endo's purported concern with public safety, not only did Endo continue to distribute original Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo also claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."[47]

192. In its Citizen Petition, Endo asserted that redesigned Opana ER had "safety advantages." However, in rejecting the Petition in a 2013 decision, the FDA found that study data "show that the reformulated version's extended-release features can be compromised when subjected to ... cutting, grinding, or chewing." The FDA also determined that "reformulated Opana ER" could also be "readily prepared for injection" and "more easily be prepared for injection[.]" In fact, the FDA warned that preliminary data—including in Endo's own studies—suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

193. Over time, evidence continued to mount that injection was becoming the preferred means of abusing Opana ER, making Opana ER *less safe* than the original formulation. Injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure.[48] In 2009,

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[47] *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl.) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 1:12-cv-01936, Doc. 18-4 (D.D.C. Dec. 9, 2012).

[48] The CDC does not know why the redesigned Opana ER causes TTP, but it notes it did not appear in other prescription opioids prepared for injection. "Thrombotic Thrombocytopenic Purpura (TTP)–Like Illness Associated with Intravenous Opana ER Abuse — Tennessee, 2012," *Morbidity and Mortality Weekly Report* (Jan. 11, 2013). The CDC suggested it could be linked to inactive ingredients that make the product more difficult to crush or grind. No reports of Opana ER and TTP occurred prior to the reformulation.

only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER increased by more than 500%.

194. Nevertheless, Endo continued to market the drug as tamper-resistant and abuse-deterrent. Indeed, a review of nationally-collected surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper resistant, even after the May 2013 denial of Endo's Citizen Petition. Endo also tracked messages that doctors took from its in-person marketing. Among the advantages of Opana ER, according to participating doctors, was its "low abuse potential."

195. In its written materials, Endo marketed Opana ER as having been ***designed*** to be crush-resistant, knowing that this would (falsely) imply that Opana ER actually ***was*** crush resistant and that this crush-resistant quality would make Opana ER less likely to be abused. For example, a June 14, 2012 Endo press release announced "the completion of the company's transition of its OPANA ER franchise to the new formulation designed to be crush resistant."[49] The press release further stated that: "We firmly believe that the new formulation of OPANA ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers."[50] In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."[51]

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[49] Ex. E to Rurka Decl., *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 12-v-1936, Doc. 18-2 at 1 (D.D.C. Dec. 9, 2012).

[50] *Id.*

[51] Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*., No. 1:12-cv-01936,Doc. 18-4 (D.D.C. Dec. 9, 2012).

196. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant."

197. In a 2016 settlement with Endo, the New York Attorney General found that statements that Opana ER was "designed to be, or is crush resistant" were false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The New York Attorney General also found that Endo failed to disclose its own knowledge of the crushability of redesigned Opana ER in its marketing to insurers and pharmacy benefit managers, which also would have impacted the availability of Opana ER in Fayette County.

3. Mallinckrodt's Deceptive Marketing of its Branded Opioids.

198. Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For example, Mallinckrodt's promotional materials stated that "the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving."[52] One member of the FDA's Controlled Substance Staff, however, noted in 2010 that hydromorphone has "a high abuse potential comparable to oxycodone" and further stated that "we predict that Exalgo will have high levels of abuse and diversion."[53]

199. In addition, with respect to Xartemis XR, Mallinckrodt's promotional materials stated that "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients."

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[52] Mallinckrodt Press Release, *FDA Approves Mallinckrodt's EXALGO® (hydromorphone HCl) Extended-Release Tablets 32 mg (CII) for Opioid-Tolerant Patients with Moderate-to-Severe Chronic Pain* (Aug. 27, 2012), available at http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2004159.

[53] http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/drugs/anestheticandanalgesicdrugproductsadvisorycommittee/ucm187490.pdf at 157-58.

G. PURDUE MISREPRESENTED ITS COOPERATION WITH LAW ENFORCEMENT.

200. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement."[54]

201. As described in Section A.1, Purdue's public stance long has been that "bad apple" patients and drug diversion to illicit secondary channels—and not widespread prescribing of OxyContin and other opioids for chronic pain—are to blame for widespread addiction and abuse. To address the problems of illicit use and diversion, Purdue promotes its funding of various drug abuse and diversion prevention programs and introduction of ADF opioids. This allows Purdue to present itself as a responsible corporate citizen while continuing to profit from the commonplace prescribing of its drugs, even at high doses for long-term use.

202. At the heart of Purdue's public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion. Purdue has consistently trumpeted this partnership since at least 2008, and the message of close cooperation is in virtually all of Purdue's recent pronouncements in response to the opioid abuse.

203. Touting the benefits of ADF opioids, Purdue's website asserts: "[W]e are acutely aware of the public health risks these powerful medications create . . . . That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid

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[54] Purdue, *Setting The Record Straight On OxyContin's FDA-Approved Label*, May 5, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

abuse and misuse . . . ."[55] Purdue's statement on "Opioids & Corporate Responsibility" likewise states that "[f]or many years, Purdue Pharma has committed substantial resources to combat opioid abuse by partnering with . . . communities, law enforcement, and government agencies."[56] And, responding to criticism of Purdue's failure to report suspicious prescribing to government regulatory and enforcement authorities, the website similarly proclaims that Purdue "ha[s] a long record of close coordination with the DEA and other law enforcement stakeholders to detect and reduce drug diversion."[57]

204. These public pronouncements create the misimpression that Purdue is proactively working with law enforcement and government authorities nationwide to root out drug diversion, including the illicit prescribing that can lead to diversion. It aims to distance Purdue from its past conduct in deceptively marketing opioids and make its current marketing seem more trustworthy and truthful.

205. Yet, Purdue, which possessed detailed information that it could use to identify suspicious prescribers and likely diversion, failed to report this activity to law enforcement. Instead, it used the data for marketing purposes. Purdue's failure to report suspicious activity was the subject of detailed reporting by the *Los Angeles Times*, which relied, in part, on internal Purdue documents and interviews with former employees and law enforcement. Since at least 2002,

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[55] Purdue website, *Opioids With Abuse-Deterrent Properties*, available at http://www.purduepharma. com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/.

[56] Purdue website, *Opioids Corporate Responsibility*, available at http://www.purduepharma.com/ news-media/opioids-corporate-responsibility/.

[57] Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, July 11, 2016, available at http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/. Contrary to its public statements, Purdue seems to have worked behind the scenes to push back against law enforcement.

Purdue has maintained a database of health care providers suspected of inappropriately prescribing OxyContin or other opioids, whom it described as "Region Zero." Physicians could be added to this database based on observed indicators of illicit prescribing such as excessive numbers of patients, cash transactions, patient overdoses, and unusual prescribing of the highest-strength pills (80 mg OxyContin pills or "80s," as they were known on the street, were a prime target for diversion). Health care providers added to the database no longer were detailed, and sales representatives received no compensation tied to these providers' prescriptions.

206. Yet, Purdue failed to cut off these providers' opioid supply at the pharmacy level—meaning Purdue continued to generate sales revenue from their prescriptions—and failed to report these providers to state medical boards or law enforcement. Purdue's former senior compliance officer acknowledged in an interview with the *Los Angeles Times* that in five years of investigating suspicious pharmacies, the company never stopped the supply of its opioids to a pharmacy, even where Purdue employees personally witnessed the diversion of its drugs.

207. The same was true of prescribers. For example, despite Purdue's knowledge of illicit prescribing from one Los Angeles clinic which its district manager called an "organized drug ring," Purdue did not report its suspicions from 2009 until 2013—long after law enforcement shut it down and not until the ring prescribed more than 1.1 million OxyContin tablets.

208. Upon information and belief, Purdue would have had information about suspicious prescribers through multiple sources. Specifically, upon information and belief, sales representatives would have the opportunity to observe suspicious activity and would become familiar with the territories they covered. In addition, Purdue reportedly obtained detailed information about individual doctors' prescribing habits obtained through a contract with a company called I.M.S. now known as IQVIA Holdings, Inc. Finally, upon information and belief,

manufacturers engaged in the practice of paying rebates and/or chargebacks to wholesalers for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts, but which information would also have signaled red flags of likely diversion.[58]

209. Purdue would have understood that its failure to report, and refrain from fueling, suspected diversion had an impact. Purdue was not entitled to be a passive (but profitable) observer of suspicious activity. It had a responsibility both to exercise due care under the circumstances, and to comply with the voluntary obligations it assumed through its public statements. In addition, Purdue has statutory and regulatory obligations, as a manufacturer of controlled substances, to monitor and report suspicious conduct in the sale and distribution of controlled substances. *See infra* Section H. This enforcement regime recognizes that drug companies often have more, and more timely, information on the distribution of their drugs that law enforcement authorities.

210. The New York Attorney General found that Purdue placed 103 New York health care providers on its No-Call List between January 1, 2008 and March 7, 2015, and that Purdue's sales representatives had detailed approximately two-thirds of these providers, some quite

[58] *The Washington Post* has described the practice as industry-wide, and a trade organization of which Defendants are members, the Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")), includes a "Contracts and Chargebacks Working Group," suggesting a standard practice. Further, at least one Marketing Defendant, Mallinckrodt, has acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors)" and promised that from this data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion." Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC at 5 (July 10, 2017), https://www.justice.gov/usao-edmi/press-release/file/986026/download. ("2017 Mallinckrodt MOA").

extensively, making more than a total of 1,800 sales calls to their offices over a six-year period . . . . "[59]

211. The New York Attorney General similarly found that Endo knew, as early as 2011, that Opana ER was being abused in New York, but certain sales representatives who detailed New York health care providers testified that they did not know about any policy or duty to report problematic conduct. The New York Attorney General further determined that Endo detailed health care providers who were subsequently arrested or convicted for illegal prescribing of opioids a total of 326 times, and these prescribers collectively wrote 1,370 prescriptions for Opana ER (although the subsequent criminal charges at issue did not involve Opana ER).[60]

H. DEFENDANTS DELIBERATELY DISREGARDED THEIR DUTIES TO PREVENT DIVERSION, REPORT, AND TERMINATE SUSPICIOUS ORDERS AND CEASE SUPPLYING SUSPICIOUS PRESCRIBERS.

1. Defendants have a duty to report suspicious orders and not to ship those orders unless due diligence disproves their suspicions.

212. By the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions. This created both a vastly and dangerously larger market for opioids in Fayette County and another lucrative opportunity for Defendants, who compounded this harm by failing to maintain effective controls against diversion and instead facilitating the supply of far more opioids than could have been justified to serve the market, and supplying opioids they knew or should have

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[59] Attorney General of the State of New York, *In the Matter of Purdue Pharma L.P.*, Assurance No.: 15-151, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 5.

[60] Attorney General of the State of New York, *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No.: 15-228, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 10-12, *available at* https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.

known were being abused or diverted. Defendants' failure to investigate, report, and terminate orders, and to report and cease supplying prescribers, that they knew or should have known were suspicious breached both their statutory and common law duties.

213. First, under the common law, the Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By filling and failing to report orders that they knew or should have realized were likely being diverted for illicit uses, Defendants breached their duty to exercise reasonable care as manufacturers of narcotic substances and both created and failed to prevent a foreseeable risk of harm to the County. As the supply of opioids and the evidence of addiction to and abuse of these drugs grew, manufacturers, distributors, and pharmacies were again reminded of both the nature and harms of opioid exposure and use.

214. Second, each Defendant assumed a duty, when speaking publically about opioids and their efforts and commitment regarding diversion of prescription opioids, to speak accurately and truthfully.

215. Third, Defendants violated their statutory obligations under Ohio law, which also incorporates the federal Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq.* and its implementing regulations. *See* O.A.C. §§ 4729-9-16(L) and 4729-9-28(I) (mandating that "[w]holesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations"). Similarly, under Ohio law, manufacturers, as a condition of their licensure, must demonstrate that "[a]dequate safeguards are assured to prevent the sale of dangerous drugs other than in accordance with section 4729.51 of the Revised Code. R.C. § 4729.53.

216. Each of the Defendants was required to register with the DEA to manufacture and/or distribute Schedule II controlled substances. *See* 21 U.S.C. § 823(a)-(b), (e); 28 C.F.R. § 0.100. Federal regulations issued under the CSA and incorporated into Ohio law pursuant to Ohio

Administrative Code §§ 4729-9-16(L) and 4729-9-28(I) further mandate that, as registrants, manufacturers and distributors alike, "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.74(b).

217. Recognizing a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act ("CSA") in 1970. The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market. Congress was concerned with the diversion of drugs out of legitimate channels of distribution and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market."[61] Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain. All registrants – which includes all manufacturers and distributors of controlled substances -- must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion. When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse. The result is the scourge of addiction that has occurred.

218. The CSA requires manufacturers and distributors of Schedule II substances like opioids to, register to manufacture or distribute opioids, maintain effective controls against diversion of the controlled substances that they manufacture or distribute, and design and operate a system to

[61] Statement of Joseph T. Rannazzisi, U.S. House Committee on Energy and Commerce Subcommittee on Health, Improving Predictability and Transparency in DEA and FDA Regulation (April 7, 2014) (quoting H.R. Rep. No. 91-1444, 1979 U.S.C.C.A.N. at 4572), https://www.dea.gov/pr/speeches-testimony/2014t/04072014t.pdf

identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA.

219. Federal regulations issued under the CSA mandate that all registrants, manufacturers and distributors alike, "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). Registrants are not entitled to be passive (but profitable) observers, but rather "shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." *Id.* Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id.* Other red flags may include, for example, "[o]rdering the same controlled substance from multiple distributors."

220. These criteria are disjunctive and are not all-inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a distributor or manufacturer need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region.

221. Defendants also have independent duties under Ohio law. The Ohio Administrative Code imposes obligations and duties upon "licensees" and "registrants" to "provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous

drugs." O.A.C. § 4729-9-05(A). These duties extend to manufacturers, wholesalers, and pharmacies alike. Under Ohio law, manufacturers, as a condition of their licensure, must demonstrate that "[a]dequate safeguards are assured to prevent the sale of dangerous drugs other than in accordance with section 4729.51 of the Revised Code. R.C. § 4729.53.

222. Under Ohio law, distributors also have a duty to detect, investigate, refuse to fill, and report suspicious orders of opioids. To that end, the Ohio Pharmacy Board requires that drug wholesalers "shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of dangerous drugs," and that, as a minimum requirement of wholesale distribution in this State, "[a] system ***shall be designed and operated to disclose orders*** for controlled substances and other dangerous drugs subject to abuse." O.A.C. § 4729-9-16(H) (emphasis added); R.C. § 4729.52 (requiring licensed wholesale distributors to comply with Ohio Board of Pharmacy security regulations); *accord* 21 U.S.C. § 823; 21 C.F.R. 1301.74 (imposing duty to monitor, detect, investigate, refuse to fill, and report suspicious orders under federal law).[62]

223. Ohio regulations further mandate that suspicious orders, defined as unusual in size ***or*** frequency ***or*** deviation from buying patterns, be reported to the Ohio Board of Pharmacy: "The wholesaler shall inform the state board of pharmacy of suspicious orders for drugs when discovered. Suspicious orders are those which, in relation to the wholesaler's records as a whole, are of unusual size, unusual frequency, ***or*** deviate substantially from established buying patterns." O.A.C. § 4729-

[62] *See also* Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Sept. 27, 2006), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-51 (hereinafter "2006 Rannazzisi Letter"); Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, Drug. Enf't Admin., U.S. Dep't of Justice, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8 (hereinafter "2007 Rannazzisi Letter").

9-16(H)(1)(e) *et seq.* (emphasis added); *see also id.* §§ 4729-9-12(G) & 4729-9-28(E). Any of the red flags identified by law trigger a duty to report; however, this list is not exclusive. Other factors—such as whether the order is skewed toward high dose pills, or orders that are skewed towards drugs valued for abuse, rather than other high-volume drugs, such as cholesterol medicines, also should alert distributors to potential problems.

224. To comply with the law, distributors also have a duty to know their customers and the communities they serve. To the extent that, through this process of customer due diligence, a distributor observes suspicious circumstances—such as cash transactions or young and seemingly healthy patients filling prescriptions for opioids at a pharmacy they supply– can trigger reasonable suspicion. A single order can warrant scrutiny, or it may be a pattern of orders, or an order that is unusual given the customer's history or its comparison to other customers in the area.

225. The FTC has recognized the unique role of wholesale distributors. Since their inception, Defendants have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, Defendants also offer their pharmacy, or dispensing, customers a broad range of added services. For example, Defendants offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. Distributor Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed

merger between Cardinal Health, Inc. and Bergen Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, Distributor Defendants have a unique insight into the ordering patterns and activities of their dispensing customers.

226. In addition, as both national pharmacy chains, as well as distributors, the Chain Pharmacies have especially deep knowledge of their retail stores' orders, prescriptions, and customers. This is underscored by the fact that Walgreens is able to sell the contents of its patients' prescriptions to data-mining companies such as IMS Health, Inc. In 2010, for example, Walgreen's fiscal year 2010 SEC Form 10-K disclosed that it recognizes "purchased prescription files" as "intangible assets" valued at $749,000,000.

227. The Chain Pharmacies, like manufacturers and other distributors, are registrants under the CSA. 21 C.F.R. § 1301.11. Under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." *See* 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." Pharmacists must ensure that prescriptions of controlled substances are "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

228. In addition, Ohio regulations require pharmacists to exercise care in this regard and are no less stringent than federal law. *See* O.A.C. § 4729-5-20(G) ("Based upon information obtained during a prospective drug utilization review, a pharmacist shall use professional judgment

when making a determination about the legitimacy of a prescription. A pharmacist is not required to dispense a prescription of doubtful, questionable, or suspicious origin."); O.A.C. § 4729-5-21(A) ("A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law."); O.A.C. § 4729-5-30(A) (same).

229. Although the obligation to "provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs" under O.A.C. § 4729-9-05(A), is imposed upon the actual pharmacy, that duty is carried out through its store-level pharmacist and other staff. *Ohio Adm. Code* § 4729-9-11 ("[a] pharmacist, prescriber, and responsible person … shall provide supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, and adequate safeguards to ensure that dangerous drugs are being distributed in accordance with all state and federal laws"). The Tenth Appellate District of the Court of Appeals of Ohio has determined that the Ohio Administrative Code "places the ultimate responsibility upon the 'registrant' … to provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs." *Linden Med. Pharm. v. Ohio State Bd. of Pharm.*, 2001 Ohio App. LEXIS 2041, at *24 (Ohio Ct. App. 11th Dist. May 8, 2001) (explaining that licensees electing to operate a business through employees are responsible to the licensing authority for their conduct").

230. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion. The Ohio Board of Pharmacy similarly has provided guidance, highlighting that pharmacists have an obligation to exercise professional judgment to determine the legitimacy of a prescription.[63]

231. Suspicious pharmacy orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others. "Pattern prescribing," where multiple individuals present prescriptions for the same drugs, for the same or similar quantities, and from the same prescriber, is likewise a red flag. Distance anomalies, when the patient and prescriber are in different locations, or non-residents of the community presenting prescriptions from the same prescriber are another warning signal. Other common red flags include shared addresses by customers receiving the same or similar prescriptions from the same prescriber on the same day, or family members receiving controlled substances prescriptions from the same prescriber, patients other than designated caregivers presenting prescriptions with another person's name, patients presenting prescriptions that the pharmacist knows or reasonably believes another pharmacy refused to fill, or patients who have health insurance paying for a controlled substances prescription with cash. Although these lists are non-exhaustive, additional types of suspicious orders include: (1) prescriptions written by a

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[63] State of Ohio Board of Pharmacy, *Sometimes We Just Say to Say No*, available at https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=2ahUKEwiS9eSu0rXdAhULeKwKHfReAGYQFjAAegQIBhAC&url=https%3A%2F%2Fwww.pharmacy.ohio.gov%2FDocuments%2FLawsRules%2FRuleChanges%2FOARRSRules%2FSometimes%2520We%2520Just%2520Have%2520to%2520Say%2520No%2520-%2520Flier.pdf&usg=AOvVaw1vf4EAyKP-9L4ivyKt2iHT

doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on earlier; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions with quantities or doses that differ from usual medical usage; (5) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (6) photocopied prescriptions; or (7) prescriptions containing different handwriting or handwriting that is too legible. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

232. Suspicious pharmacy orders are red flags for if not direct evidence of diversion.

233. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the Chain Pharmacies themselves. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing. Pharmacies, at a corporate level, may observe, for example, many customers paying with cash, many customers receiving the same strength of prescription, and many customers with the same diagnosis code, as well as increases in the number of controlled substances prescriptions being presented to a given pharmacy.

234. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

235. Pharmacies are "often the last major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market and it is "incumbent upon pharmacies to ensure that controlled substances are only dispensed pursuant to valid prescriptions issued for legitimate medical purposes in the usual course of professional

practice."[64] Further, "[p]harmacists many times have more experience concerning the dangers of drugs than man treating physicians who do not undergo extensive training with regard to pharmacology." *Thompson v. Knoblech*, 2016 Ohio Misc., LEXIS 6369, *10 Case Mo. 14 CVA05-4879, Ct. of Common Pleas, Franklin County (May 11, 2016). Their experience and training enables them to anticipate when "a prescription for a patient could have catastrophic consequences." *Id.* And, they fulfill an important role in "act[ing] as another layer of safety for the patient." *Id.*[65]

236. In sum, Defendants, due to the position of special trust and responsibility afforded them by their status as registrants in the distribution chain of controlled substances, have several responsibilities under state and federal laws with respect to suspicious orders of opioids. First, they must set up a system designed to detect such orders. That would include reviewing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. All flagged orders must be reported to relevant enforcement authorities. Further, they must also stop shipment of any order which is flagged as suspicious and

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[64] Declaration of Joseph Rannazzisi, *Holiday CVS, LLC d/b/a CVS/Pharmacy Nos. 5195/219 v. Eric Holder, Jr. et al.*, No. 1:12-cv-191, Doc. 19-6 ¶ 10 (D.D.C. Feb. 24, 2012).

[65] The Chain pharmacies have promoted themselves as filling that role. Helena Foulkes, President, CVS Pharmacy, said that "[a]t CVS Pharmacy we know pharmacists play an important role in providing our patients with timely and relevant information about their prescription medications." Similarly, Alex Gourlay, Co-Chief Operating Officer of Walgreens Boots Alliance and President of Walgreens, touted the network as "recogniz[ing] that pharmacists do more than dispense medications – they are key members of the patient care teams . . . ." https://cvshealth.com/newsroom/press-releases/cvs-health-introduces-new-pbm-performance-based-pharmacy-network-focused

only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.[66]

237. These statutes and regulations reflect a standard of conduct and care below which reasonably prudent manufacturers, distributors, and pharmacies, would not fall. Together, these laws set standards of care that make clear that wholesalers, pharmacies, and manufacturers of controlled substances alike possess, and are expected to possess, specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the distribution chain is not properly controlled.

238. Further, these laws set standards of care that make clear that Defendants have a duty and responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

239. All Defendants have a duty to, and are expected, to be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.

4. Defendants understood the importance of their reporting and due diligence obligations.

240. All Defendants were well aware they had an important role to play in the controlled system of prescription opioid distribution, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

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[66] *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007) (applying federal requirements no less stringent than those of Ohio); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206 (D.C. Cir. 2017) (same).

241. In fact, trade organizations to which Defendants belong have acknowledged that wholesale distributors such as Defendants have been responsible for reporting suspicious orders for more than 40 years.[67] The Healthcare Distribution Management Association ("HDMA," now known as the Healthcare Distribution Alliance ("HDA")), a trade association of pharmaceutical distributors to which Marketing Defendants, Cardinal, McKesson, AmerisourceBergen, and CVS belong, as well as the National Association of Chain Drug Stores, whose board membership includes representatives of Walgreens and CVS have long taken the position that distributors have responsibilities to "prevent diversion of controlled prescription drugs" not only because they have statutory and regulatory obligations do so, but "as responsible members of society."[68] Guidelines established by the HDA also explain that distributors, "[a]t the center of a sophisticated supply chain . . . are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."[69]

242. The DEA also repeatedly has made clear that Defendants' obligations under federal law, mirrored in and incorporated by Ohio law, *see infra* Section H.1, obligate them to report and decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the

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[67] *See* Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharmaceuticals, Inc. v. Drug Enforcement Administration*, 2012 WL 1321983, at *4 (D.C. Cir. Apr. 4, 2016) (stating that regulations "in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA . . .") (emphasis omitted).

[68] *See Amicus Curiae* Br. of Healthcare Distribution Management Association (HDMA) in Support of Cardinal Health, Inc.'s Motion for Injunction Pending Appeal, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 at 4; Brief for Healthcare Distribution Management Association and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharmaceuticals, Inc. v. Drug Enforcement Administration*, 2012 WL 1321983, at *2 (D.C. Cir. Apr. 4, 2016).

[69] Healthcare Distribution Management Association (HDMA) *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, *filed in Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App'x B at 1).

internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes.[70] Defendants AmerisourceBergen, Cardinal, and McKesson each attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.

243. The DEA also, for example, advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances (which included the Distributor Defendants) that they are "one of the key components of the distribution chain. If the closed system is to function properly . . . distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as . . . the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[71] The DEA's September 27, 2006 letter also expressly reminded them that registrants, *in addition* to reporting suspicious orders, have a

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[70] Drug Enf't Admin., *Distributor Conferences*: https://www.deadiversion.usdoj.gov/mtgs/distributor/index.html; Drug Enf't Admin., *anufacturer Conferences*, https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/index.html; Drug Enf't Admin., *National Conference on Pharmaceutical and Chemical Diversion*, https://www.deadiversion.usdoj.gov/mtgs/drug_chemical/index.html; Drug Enf't Admin., *Diversion Awareness Conferences*, https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/index.html.

[71] *See* 2006 Rannazzisi Letter ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.").

"statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[72]

244. The DEA sent another letter to distributors and manufacturers alike on December 27, 2007, reminding them that, as registered manufacturers and distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to "maintain effective controls against diversion" and "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[73] The DEA's December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and "some criteria to use when determining whether an order is suspicious."

281. Through presentations at industry conferences and on its website, the DEA provided detailed guidance to distributors on what to look for in assessing their customers' trustworthiness. For example, DEA published "Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances,[74] which suggests that distributors examine:

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[72] *See* 2006 Rannazzisi Letter.

[73] *See* 2007 Rannazzisi Letter.

[74] U.S. Dept. of Justice DEA, Diversion Control Division website, Pharmaceutical Industry Conference (Oct 14 & 15, 2009), https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/; *Suggested Questions a Distributor should ask prior to shipping controlled substances*, Drug Enforcement Administration (*available at* https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq., *Pharmaceutical Production Diversion: Beyond the PDMA,*

- What is the pharmacy's ratio of controlled vs. non-controlled orders?
- Does the pharmacy order a full variety of controlled substances and are they fairly evenly dispersed? If not, why the disparity?
- What are the hours of operation of the pharmacy?
- Does the pharmacy offer a full assortment of goods to its customers (e.g., over-the-counter drugs, snacks, cosmetics, etc.)?
- Does the pharmacy have security guards on the premises?
- What methods of payment does the pharmacy accept (cash, insurance, Medicaid, and in what ratios)?
- Does the pharmacy order from other suppliers as well? If so, why and what controlled substances?
- If this is a new account, why does the pharmacy want you to be their supplier?
- If you are not the only supplier, what controlled substances will the pharmacy be ordering from you, in what quantities, in what time frame, and will they be ordering these same products from other suppliers?
- What ratio will you be supplying compared to other suppliers?
- Does the pharmacy serve out of state customers?
- Does it serve pain clinics?
- Are there particular practitioners who constitute most of the prescriptions it fills and who are these practitioners
- Does the pharmacy have any exclusive contracts, agreements, arrangements, etc., with any particular practitioner, business group, investors, etc.? If so, explain those arrangements and/or obtain copies of those agreements.

245. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt $35 million for

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Purdue Pharma and McGuireWoods LLC, (*available at* https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.[75]

246. In the press release accompanying the settlement, the Department of Justice stated: "Mallinckrodt did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone . . . . Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . . Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands. . . ."[76]

247. Among the allegations resolved by the settlement, the government alleged "Mallinckrodt failed to design and implement an effective system to detect and report 'suspicious orders' for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders."[77]

248. The 2017 Mallinckrodt MOA further details the DEA's allegations regarding Mallinckrodt's failures to fulfill its legal duties as an opioid manufacturer:

> With respect to its distribution of oxycodone and hydrocodone products, Mallinckrodt's alleged failure to distribute these controlled substances in a

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[75] *See* 2017 Mallinckrodt MOA.

[76] *See* Press Release, U.S. Dep't of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

[77] *Id.*

manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:

i. conduct adequate due diligence of its customers

ii. detect and report to the DEA orders of unusual size and frequency;

iii. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:

1. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,

2. orders that purchased a disproportionate amount of a substance which is most often abused compared to other products, and

3. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware;

iv. use "chargeback" information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and

v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.[78]

249. In connection with that settlement, Mallinckrodt admitted that "[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion,

[78] 2017 Mallinckrodt MOA at 2-3.

including a requirement that it review and monitor these sales and report suspicious orders to DEA."[79] Mallinckrodt further stated that it "recognizes the importance of the prevention of diversion of the controlled substances they manufacture" and agreed that it would "design and operate a system that meets the requirements of 21 C.F.R. 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product." Mallinckrodt specifically agreed "to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers."[80]

250. Mallinckrodt also acknowledged that at certain times prior to January 1, 2012, "certain aspects of Mallinckrodt's system to monitor and detect suspicious orders did not meet the standards outlined in letter from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007."[81]

251. In connection with the investigation of Mallinckrodt, the Department of Justice and DEA determined that Mallinckrodt ignored its responsibility to report suspicious orders of as many as 500 million of its pills that were sent to Florida from 2008 and 2012, which was 66% of all oxycodone sold in the state. Mallinckrodt, through its internal sources, knew that opioids it was supplying were being used to fill suspicious orders in Florida, and knew or should have known that those opioids were being diverted into Ohio communities. In light of a crack-down on in-state pill mills by Ohio authorities, as well as Ohio's implementation of a Prescription Drug Monitoring Program, traffickers in Ohio routed orders through Florida pharmacies or prescribers for diversion back into Ohio communities on a route that became known as the "Florida Pipeline" or

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[79] *Id.* at 1.

[80] *Id.*

[81] *Id.* at 3-4.

"OxyContin Express," or "Blue Highway," after the color of opioids Mallinckrodt manufactured.[82] Moreover, Mallinckrodt recognized in November 2010 that 68% of the purchases by one of its distributors, Cincinnati-based KeySource Medical, Inc., were for prescription opioids, and that 91% of this customer's purchasers were sent to Florida.[83]

252. Mallinckrodt also acknowledged it had other information that would have alerted it to potential diversion. Specifically, Mallinckrodt acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants." As part of the settlement, Mallinckrodt agreed that, from this data, it would "report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion."[84]

5. Despite repeated admonitions, Defendants have repeatedly violated their reporting and due diligence obligations.

253. Mallinckrodt was not alone in being fined by the DEA. Other Defendants have faced repeated enforcement actions for their failure to comply with their obligations to report and decline suspicious orders, making clear both that they were repeatedly reminded of their duties, and that they frequently failed to meet them.

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[82] Decl. of DEA Diversion Investigator Christopher Kresnak, *KeySource Medical Inc. v. Holder*, No. 1:11-cv-00393, Doc. 9-2 ¶ 3 (S.D. Ohio June 30, 2011).

[83] United States' Opposition to Plaintiff's Motion for a Preliminary Injunction, *KeySource Medical Inc. v. Holder*, No. 1:11-cv-00393, Doc. 9 at 6 (S.D. Ohio June 30, 2011).

[84] 2017 Mallinckrodt MOA at 5

254. Governmental agencies and regulators have confirmed (and in some cases Defendants have admitted) that Defendants did not meet their obligations, and have uncovered especially blatant wrongdoing.

255. In May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. These included a number of actions against AmerisourceBergen, Cardinal, and McKesson:

a. On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

b. On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

c. On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

d. On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

e. On January 30, 2008, the DEA issued an *Order to Show Cause* against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

f. On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 McKesson MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

g. On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn, Lakeland, Swedesboro and Stafford Facilities. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

h. On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone; and

i. On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center.

256. CVS, too, is a repeat offender and recidivist: the company has paid fines totaling over $40 million as the result of a series of investigations by the DEA and the United States Department of Justice ("DOJ"). It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations under the CSA.

257. As recently as June 2018, CVS Pharmacy, Inc. agreed to pay $1.5 to settle civil penalty claims stemming from a DEA investigation of CVS pharmacy stores in Nassau and Suffolk Counties on Long Island. The DEA's investigation revealed that these pharmacies failed to timely report the loss or theft of controlled substances, including hydrocodone, one of the most commonly diverted controlled substances.

258. This fine was preceded by numerous others throughout the country.

259. Just last year, in July 2017, CVS entered into a $5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.

260. In February 2016, CVS paid $8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filling prescriptions with no legitimate medical purpose.

261. In October 2016, CVS paid $600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.

262. In September 2016, CVS entered into a $795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.

263. In June 2016, CVS agreed to pay the DOJ $3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.

264. In August 2015, CVS entered into a $450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.

265. In May 2015, CVS agreed to pay a $22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need."

266. In September 2014, CVS agreed to pay $1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.

267. In August 2013, CVS was fined $350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.

268. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.

269. CVS saw huge increases in the quantity of oxycodone it dispensed in Florida from 2006 to 2010. Starting with an already high baseline, a single CVS ordered approximately four times the amount of oxycodone a typical pharmacy orders in one year in 2006. By 2010, the same pharmacy's 10-month history showed quantities more than thirty times the amount of oxycodone a typical pharmacy orders in one year, and the pharmacy's supervisor could not explain why the volume was so high. During that time, Cardinal was the pharmacy's main distributor, and two of CVS's Florida pharmacies were among Cardinal's top four retail pharmacy customers, dispensing a staggering amount of oxycodone compared to Cardinal's other Florida customers. Interviews

with employees of these pharmacies revealed that they routinely observed red flags and obvious signs that they were filling illegitimate prescriptions. One set a daily limit of oxycodone 30mg prescriptions the pharmacy would fill each day, basing the limit on the amount in stock that day, so as to ensure that the "real pain patients" could get their prescriptions filled.[85] The pharmacy usually reached its limit by lunchtime each day, and at times within a 30 minutes of opening. Customers, aware that prescriptions were first come, first serve, would line up outside the store as early as 7:45 AM. An employee acting as "bouncer" included escorting off the premises customers who were "hooked" on opioids and became belligerent if their prescriptions were refused among his job duties.[86] Although CVS/Caremark, Inc. had in place dispensing guidelines for controlled substances prescriptions, these guidelines were not followed at these stores. Rather, they controlled substances dispensed prescriptions despite the existence of "warning signs" in the guidelines.[87]

270. CVS acknowledged in 2012 that it was "aware of the pill mill and/or pain clinic situation and the diversion of controlled substances, primarily oxycodone, in Florida," and was advised by the DEA of typical red flags.[88] CVS's and Cardinal's failure to take action to report or halt the distribution of these opioids reflect systemic failure in their compliance and also would have permitted the migration of these opioids to other jurisdictions, including Ohio.

271. Walgreens also has been penalized for serious and flagrant violations of the CSA. On February 12, 2012, the DEA issued an Order to Show Cause and Immediate Suspension of

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[85] Declaration of Joseph Rannazzisi, *Holiday CVS, LLC d/b/a CVS/Pharmacy Nos. 5195/219 v. Eric Holder, Jr. et al.*, No. 1:12-cv-191, Doc. 19-6 ¶¶ 38-41 (D.D.C. Feb. 24, 2012).

[86] *Id.* ¶ 41.d.

[87] *Id.* ¶¶ 48 & 56.

[88] Declaration of Joseph Rannazzisi, *Holiday CVS, LLC d/b/a CVS/Pharmacy Nos. 5195/219 v. Eric Holder, Jr. et al.*, No. 1:12-cv-191, Doc. 19-6 ¶¶ 27-28 (D.D.C. Feb. 24, 2012).

Registration against Defendant Walgreens' Jupiter, Florida distribution center ("Jupiter Center"), for failure to maintain effective controls against the diversion of opioids. The DEA found, among other things, that the Jupiter Center failed to conduct adequate due diligence and should have known that the Walgreens pharmacies were dispensing controlled substances, including opioids, for other than legitimate medical purposes.

272. In June 2013, Walgreens agreed to the largest settlement in DEA history at the time—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA at the Jupiter Center and six Walgreens retail pharmacies in Florida, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black market sales. The Department of Justice, in describing the settlement, explained that the conduct at issue included Walgreens' "alleged failure to sufficiently report suspicious orders was a systematic practice that resulted in at least tens of thousands of violations and allowed Walgreens' retail pharmacies to order and receive at least three times the Florida average for drugs such as oxycodone."[89]

273. Walgreens' Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount. In addition to the monetary payment, the Jupiter, Florida distribution center lost its authority to distribute or dispense controlled substances, including opioids, for two years. This revocation ended in 2014.

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[89] Press Release, U.S. Attorney's Office S. Dist. of Fla., *Walgreens Agrees To Pay A Record Settlement Of $80 Million For Civil Penalties Under The Controlled Substances Act*, U.S. Dep't of Just. (June 11, 2013), https://www.justice.gov/usao-sdfl/pr/walgreens-agrees-pay-record-settlement-80-million-civil-penalties-under-controlled.

274. The Jupiter Center supplied prescription opioids to two Walgreens pharmacies in Oviedo, Florida, one of which increased its oxycodone prescriptions from 6,600 dosage units in June 2010 to 169,780 dosage units in June 2011. Multiple arrests at the Oviedo Walgreens for illicit sales prompted the local chief of police to write letters to the Chairman and CEO of Walgreens and asked for their assistance in fighting the prescription drug epidemic. In the letter, the police chief reported that at both locations drugs were "sold, distributed as payment, crushed, and snorted, liquefied and injected, or multiple pills swallowed while in the parking lot of your pharmacies."[90]

275. Defendant Walgreens' Jupiter Center continued to supply prescription opioids to the Oviedo pharmacies, and increased its quantities of 30 mg oxycodone from 73,300 tablets in February 2011, to 145,300 dosage units in July 2011. The Jupiter Center nearly doubled its distribution of oxycodone to one of these pharmacies within a six month period.

276. The Jupiter Center, along with Defendant Walgreens' headquarters, ignored warnings and concerns from its own employees about large shipments of opioids. In January 2011, the Center's Function Manager, who was responsible for all Schedule II drug operations (including opioids), sent an email to the manager of Walgreens' drug stores at its headquarters about the suspiciously "large quantity," of oxycodone that was being ordered by three stores in Florida.[91] The Jupiter Center continued to supply opioids to these locations, and provided a Walgreens' pharmacy in a town of less than 3,000 people, 285,800 30 milligram doses of oxycodone in January 2011. Despite the warning from an employee, Defendant Walgreens did not report any of these orders as suspicious.

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[90] In the Matter of Walgreens Co. *Order to Show Cause*, September 13, 2012.

[91] *Id.*

277. Instead, Walgreens corporate officers turned a blind eye to these abuses. In fact, corporate attorneys at Walgreens suggested, in reviewing the legitimacy of prescriptions coming from pain clinics, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance,"[92] underscoring Walgreens' attitude that profit outweighed compliance with the CSA or the health of communities.

278. According to the Order to Show Cause, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year, and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.

279. Walgreens' misconduct was not limited to Florida. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk—despite the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.

280. More recently, Defendant McKesson admitted to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it "did not identify or report to [the] DEA certain orders placed by certain pharmacies

[92] *Id.*

which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[93] Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)."[94] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers" including the McKesson Distribution Center located in Washington Court House, Ohio. Due to these violations, McKesson agreed to a partial suspension of its authority to distribute controlled substances from the Washington Court House, Ohio facility (among other facilities).[95] Washington Court House, Ohio is the seat of Fayette County and, upon information and belief, McKesson's Washington Courthouse distribution center supplied opioids locally as well as to more distant customers.

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[93] Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) (hereinafter "2017 Settlement Agreement and Release") ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), available at https://www.justice.gov/opa/press-release/file/928471/download.

[94] *Id.*

[95] Other facilities included McKesson's distribution centers in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland, FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Santa Fe Springs, CA; and West Sacramento, CA.

281. As the *Washington Post* and *60 Minutes* have reported, DEA staff recommended a much larger penalty, as much as a billion dollars, and delicensing of certain facilities.[96] A DEA memo outlining the investigative findings in connection with the administrative case against the 12 McKesson distribution centers included in the 2017 Settlement stated that McKesson "[s]upplied controlled substances in support of criminal diversion activities"; "[i]gnored blatant diversion"; had a "[p]attern of raising thresholds arbitrarily"; "[f]ailed to review orders or suspicious activity"; and "[i]gnored [the company's] own procedures designed to prevent diversion."[97] The Washington Court House distribution center was among the warehouses investigators found "were supplying pharmacies that sold to criminal drug rings."[98]

282. Even the far lessor-than recommended civil penalty against McKesson, a $150 million fine, was record breaking. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in four different states. Though this penalty too, was far less severe than investigators had recommended, as the DOJ explained, these "staged suspensions" are nevertheless "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."[99]

283. Following the 2017 settlement, McKesson shareholders made a books and records request of the company. According to a separate action pending on their behalf, the Company's records show that the Company's Audit Committee failed to monitor McKesson's information

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[96] Lenny Bernstein and Scott Higham, "'*We Feel Like Our System Was Hijacked': DEA Agents Say a Huge Opioid Case Ended in a Whimper*, Washington Post (Dec. 17, 2017).

[97] *Id.*

[98] *Id.*

[99] Department of Justice, "McKesson Agrees to Pay Record $150 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs, (Jan. 17, 2017) https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders.

reporting system to assess the state of the Company's compliance with the CSA and McKesson's 2008 Settlements. More particularly, the shareholder action alleges that the records show that in October 2008, the Audit Committee had an initial discussion of the 2008 Settlements and results of internal auditing, which revealed glaring omissions; specifically:

a. some customers had "not yet been assigned thresholds in the system to flag large shipments of controlled substances for review";

b. "[d]ocumentation evidencing new customer due diligence was incomplete";

c. "documentation supporting the company's decision to change thresholds for existing customers was also incomplete"; and

d. Internal Audit "identified opportunities to enhance the Standard Operating Procedures."

284. Yet, instead of correcting these deficiencies, after that time, for a period of more than four years, the Audit Committee failed to address the CSMP or perform any more audits of McKesson's compliance with the CSA or the 2008 Settlements, the shareholder action's description of McKesson's internal documents reveals. During that period of time, McKesson's Audit Committee failed to inquire whether the Company was in compliance with obligations set forth in those agreements and with the controlled substances regulations more generally.

285. In short, McKesson, was "neither rehabilitated nor deterred by the 2008 [agreement],'" as a DEA official working on the case noted.[100] Quite the opposite, "'their bad acts continued and escalated to a level of egregiousness not seen before.'"[101] According to statements of "DEA investigators, agents and supervisors who worked on the McKesson case" reported in the *Washington Post*, "the company paid little or no attention to the unusually large and frequent orders

[100] *Id.* (alteration in original).

[101] *Id.* (quoting a March 30, 2015 DEA memo).

placed by pharmacies, some of them knowingly supplying the drug rings."[102] "Instead, the DEA officials said, the company raised its own self-imposed limits, known as thresholds, on orders from pharmacies and continued to ship increasing amounts of drugs in the face of numerous red flags."[103]

286. Further, in a *60 Minutes* interview in the fall of 2017, former DEA agent Joe Rannazzisi described Defendants' industry as "out of control," stating that "[w]hat they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die. "[104] He further explained that:

> JOE RANNAZZISI: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.
>
> [INTERVIEWER]: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.
>
> JOE RANNAZZISI: That's not an implication, that's a fact. That's exactly what they did.[105]

287. Another DEA veteran similarly stated that these companies failed to make even a "good faith effort" to "do the right thing."[106] He further explained that "I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us."[107]

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[102] *Id.*

[103] *Id.*

[104] Bill Whitaker, *Ex-DEA Agent : Opioid Crisis Fueled by Drug Industry and* Congress, CBS News (Oct. 17, 1017), https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-Congress

[105] *Id.*

[106] *Id.*

[107] *Id.*

288. At a hearing before the House of Representatives' Energy and Committee Subcommittee on Oversight and Investigations on May 8, 2018, the chief executives of McKesson and Cardinal, among others, testified regarding their anti-diversion programs and their roles in the opioid epidemic. The Chairman of Miami-Luken alone acknowledged, in response to questions, that his company failed in the past to maintain effective controls to prevent diversion and that its actions contributed to the opioid crisis. He also testified that Miami-Luken had severed relationships with many customers that continue to do business with other distributors. Despite the frequent prior enforcement actions described above, neither McKesson nor Cardinal admitted any deficiencies in their compliance. In fact, both executives' answers confirmed gaps and breakdowns in past and current practices.

289. For example, Cardinal's former Executive Chairman, George Barrett, denied that "volume in relation to size of population" is a "determining factor" in identifying potentially suspicious orders. Despite regulatory and agency direction to identify, report, and halt suspicious *orders*, Cardinal focused on whether a pharmacy was legitimate, not whether its orders suggested evidence of diversion. Despite a Cardinal employee flagging an especially prolific pharmacy as a potential pill mill in 2008, the Subcommittee found no evidence that Cardinal took any action in response. In addition, Cardinal increased another pharmacy's threshold twelve times, but could not explain what factors it applied or how it made decisions to increase thresholds.

290. According to records produced to the Subcommittee, McKesson's due diligence file on one of the pharmacies in West Virginia that it supplied with a massive volume of opioids consisted of a single page. Despite McKesson's claim that it (a) reviewed every single customer for high volume orders of certain drugs; (b) set a threshold of 8,000 pills per month; and (c)

examined and documented every order over that threshold, the company still shipped 36 times the monthly threshold to one pharmacy—9,500 pills *per day*.

291. The above violations reflect a pervasive pattern and practice over the last decade of failing to report and stop suspicious orders from which Defendants' operations in Ohio and the supply of opioids into Fayette County would not have been exempt. In addition, these violations of federal law and regulations also constituted violations of Ohio law.

4. Defendants worked together to sustain their market and boost their profits.

292. As leading wholesale distributors, Distributor Defendants had close financial relationships with both manufacturers and customers, for whom they provide a broad range of value-added services that render them uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by manufacturers to their downstream customers who ultimately dispense the drugs and would be difficult and costly for the dispenser to reproduce. For example, "[w]holesalers have sophisticated ordering systems that allow customers to electronically order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock." *Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998). Through their generic source programs, wholesalers are also able "to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers." Wholesalers also offer marketing programs, patient services, and other software to assist their dispensing customers.

293. Wholesaler Defendants had financial incentives from manufacturers to distribute higher volumes, and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers

based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill, in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, the increased sales volumes result in increased profits.

294. Upon information and belief, each of the Defendants also worked together through trade or other organizations, such as the HDA, the National Association of Chain Drugstores ("NACDS"),[108] and Pain Care Forum ("PCF"), to safeguard the market for Marketing Defendants' opioids and the distribution of opioids.

295. Upon information and belief, the HDA and the Wholesaler Defendants sought the active membership and participation of manufacturers by advocating that one of the benefits of membership included the ability to develop direct relationships between manufacturers and distributors at high executive levels. The HDA touted the benefits of membership to manufacturers, advocating that membership included the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections."[109]

296. After becoming members, the wholesalers and manufacturers alike were eligible to participate on councils, committees, task forces and working groups, including:

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[108] The National Association of Chain Drug Stores (NACDS) is a national, not-for-profit trade association that represents traditional drug stores and supermarkets and mass merchants with pharmacies. Walgreen Company and CVS Health are members and/or have representatives on the Board of Directors of NACDS.

[109] Manufacturer Membership Benefits, Healthcare Distribution Alliance, available at https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en..

a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."

b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributors and manufacturer members.

c. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management and quality improvement." Participation in this committee includes distributors and manufacturer members.

d. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.

e. Contracts and Chargebacks Working Group: "This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals." Participation in this group includes manufacturer and distributor members.[110]

297. HDA also offers a multitude of conferences, including annual business and leadership conferences. HDA advertises these conferences to manufacturers as "bring[ing] together high-level executives, thought leaders and influential managers . . . to hold strategic

[110] Councils and Committees, Healthcare Distribution Alliance, available at https://www.healthcaredistribution.org/about/councils-and-committees

business discussions on the most pressing industry issues."[111] These conferences provided HDA members "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry"[112] and an opportunity for Defendants to work together.

298. Defendants also worked together through joint efforts of the HDA and NACDS. The respective CEOs of the HDA and NACDS have spoken with one voice, with respect to portraying their members as committed to safeguarding the integrity of the supply chain when opposing efforts to promote the importation of prescription drugs as a means of mitigating the escalating costs of medications. These statements support the inference that Defendants worked together in other ways as well to mislead the public regarding their commitment to complying with their legal obligations and safeguarding against diversion.

299. Defendants also coordinated in other ways, including, according to articles published by the Center for Public Integrity and the Associated Press, the Pain Care Forum—whose members include, upon information and belief, the HDA—which has been lobbying on behalf of opioid manufacturers and distributors for "more than a decade."[113] This coordination in their lobbying further supports an inference that Defendants worked together in other ways, including through the enterprise described in this Complaint.

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[111] Business and Leadership Conference—Information for Manufacturers, Healthcare Distribution Alliance, available at https://www.healthcaredistribution.org/events/2015-business-and-leadership-conference/blc-for-manufacturers.

[112] *Id.*

[113] Matthew Perrone, Pro-Painkiller echo chamber shaped policy amid drug epidemic, The Center for Public Integrity (Sept. 19, 2017), available at https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo-chamber-shaped-policy-amid-drug-epidemic; PAIN CARE FORUM 2012 Meetings Schedule, (last updated Dec. 2011) (showing Covidien, Mallinckrodt LLC's parent company until mid-2013, as a member in 2012), available at https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf

300. Taken together, the interaction and length of the relationships between and among the Defendants reflect a deep level of interaction and cooperation between two groups in a tightly knit industry. The Defendants were not operating in isolation or groups forced to work together in a closed system. They operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

301. The HDA, NACDS, and the Pain Care Forum are examples of the overlapping relationships and concerted joint efforts to accomplish common goals, and demonstrate that the leaders of each of the Defendants were in communication and cooperation.

302. Publications and guidelines issued by the HDA confirm that Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (the "Industry Compliance Guidelines") regarding diversion. As the HDA explained in an *amicus* brief, the Industry Compliance Guidelines were the result of "[a] committee of HDMA members contribut[ing] to the development of this publication" beginning in late 2007.[114]

303. Defendants were also a part of a decision-making scheme seeking to increase sales through a systematic refusal to maintain effective controls against diversion and identify suspicious orders and report them to the DEA.

304. Defendants worked to control the flow of information and influence state and federal governments to pass legislation that supported the use of opioids and limited the authority

[114] *See Amicus Curiae* Br. of Healthcare Distribution Management Association (HDMA) in Support of Cardinal Health, Inc.'s Motion for Injunction Pending Appeal, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 at 5.

of law enforcement to rein in illicit or inappropriate prescribing and distribution. They did this through their participation in the PCF and HDA.

305. Defendants thus knew that their own conduct could be reported by other distributors and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency in their dealings with DEA.

306. The desired consistency was achieved. As described below, Defendants failed to report suspicious orders and the flow of opioids continued unimpeded.

5. Defendants ignored red flags of abuse and diversion.

307. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view, but is in the possession of Defendants.

308. Yet, publicly available information confirms that Defendants funneled far more opioids into the County than could have been expected to serve legitimate medical use, and ignored other red flags of suspicious orders. This information, along with the information known only to Defendants, would have alerted them to potentially suspicious orders of opioids in and affecting Fayette County.

309. As discussed above, Fayette County had an opioid prescription rate exceeding its population from 2006 to 2015, and that rate has remained high —an average of 99.2 prescriptions per 100 people—thereafter.

310. All told, Fayette County, with an average population from 2010 to 2017 of approximately 29,021, received a total of 15,807,728 retail doses of opioid analgesics. This amounted to approximately 141 doses per opioid patient. The volume of opioids distributed in Fayette County is so high as to raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses.

311. Given this, and the additional red flags described below, Defendants would, upon information and belief, have been aware of suspicious orders and prescribers. The County's information and belief rests upon the following facts:

(a) Defendants have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;

(b) Manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;

(c) Manufacturers and distributors regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion;

(d) Pharmacies have access to the prescriptions themselves and detailed prescription and transaction histories, as well as the opportunity to observe patients who come in to their stores;

(e) Upon information and belief, Distributor Defendants were the primary source of prescription opioids in Fayette County, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area;

(f) Walgreens and CVS have been penalized for their illegal prescription opioid practices, and the widespread nature of these violations suggests they are the product of national policies and practices, including the performance metrics and prescription quotas adopted for their retail stores;

(g) Mallinckrodt and a number of the Distributor Defendants have admitted to or been subject to enforcement actions for systemic failures in their compliance with controlled substances obligations, from which their actions in Fayette County would not have been exempt; and

(h) According to testimony by a Cardinal former Executive Chairman of the Board at a hearing before the House of Representatives' Energy and Committee Subcommittee on Oversight and Investigations on May 8, 2018, a distributor has the ability to request drug dispensing reports, which include all drugs dispensed by a pharmacy, not only those by Cardinal, and had requested such reports in the past. Upon information and belief, other wholesale distributors could request similar reports.

312. At all relevant times, Defendants were in possession of data or information that allowed them to track prescribing patterns over time. For example, Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help Defendants identify suspicious orders or customers who were likely to divert prescription opioids. The "know your customer" questionnaires informed Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

313. Upon information and belief, at all relevant times, the Defendants were in possession of national, regional, state, and local prescriber- and patient-level data that allowed them to track prescribing patterns over time. Purdue obtained detailed data about individual doctors' prescribing patterns from I.M.S., which it used to target its marketing. Moreover, as a routine practice, "[p]harmaceutical companies monitor the return on investment of detailing - and all promotional efforts - by prescription tracking."[115] Companies such as IMS Health, Dendrite, Verispan, and Wolters Kluwer, referred to as "information distribution companies," "health information organizations" or "data vendors" purchase prescription records from pharmacies, the majority of which sell these records.[116] The largest such company, IMS Health, has been described

[115] Joint Appendix, *Sorrell v. IMS Health*, No. 10-779, 2011 WL 687134, at *388-89 (Feb. 22, 2011) (Fugh-Berman A, Ahari S (2007) Following the Script: How Drug Reps Make Friends and Influence Doctors. PLoS Med 4(4): e150. doi:10.1371/journal.pmed.0040150).

[116] *Id.* at 389.

as procuring records on about 70% of prescriptions filled in community pharmacies.[117] Pharmaceutical companies are the primary customers for the prescribing data sold by these vendors.[118]

314. The same information, which is often used to identify "high prescribers" for purposes of marketing efforts, would have allowed Defendants to identify pill mills and red flags of abuse or diversion. In fact, one of the data vendor's experts previously testified that "a firm that sells narcotic analgesics was able to use prescriber-identifiable information to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product."[119]

315. Pharmacies such as those operated by CVS and Walgreens have particularly detailed information that would have alerted them to red flags of abuse and diversion. As noted above, both CVS and Walgreens would have had particularly detailed information due to the integration of their operations at different levels of the supply chain. Walgreens describes its Ohio distribution center as having "a very sophisticated computer-driven automated storage and retrieval system" and high tech "inventory management system" that "connects [its] stores and [its] distribution centers."[120] Accordingly, upon information and belief, Walgreens possessed real-time data that fully and accurately depicted the exact amounts of pills, pill type, and anticipated "customer" order threshold for its own stores. It is conceivable that such data monitoring systems could, and likely did, track and/or record facially suspicious orders.

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[117] *Id.*

[118] *Id.*

[119] *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 705207, *467-471 (Feb. 22, 2011); *see also* Joint Appendix, *Sorrell v. IMS Health*, No. 10-779, 2011 WL 687134, at *204 (Feb. 22, 2011).

[120] Toledo Business Journal, *$135 million Walgreen Distribution Center* Targeted, (Sept. 1, 2000), http://www.toledobiz.com/Files/major_stories/tbj_featured0009walgreens.html

316. Upon information and belief, Walgreens utilized Central Pharmacy Operations that provided "central fill" services to its "Well Experience" locations for a period of time beginning as early as 2009. As described herein, these Central Pharmacy Operations locations served as both distributors and dispensaries of opioids. Central Pharmacy Operation centers first existed in select states, but later spread nationwide. They currently provide pharmacy support services including customer registration, data entry, patient and provider review, data verification, and telephonic customer counseling.

317. The use of "central fill" practices allowed the company to break down the face-to-face relationship between the patient and pharmacist by outsourcing things like bottling, labeling, prescription review, and data verification. Thus, the Central Pharmacy Operation centers acted as both distributors and dispensaries by providing the Well Experience locations medications to dispense, and also as a dispensing pharmacy, mailing the medication to the Well Experience locations to be given to the customer. In addition to the above, Walgreens is known to have traditional distribution centers, one of which is in Perrysburg, Ohio. Upon information and belief, Walgreens acted as a wholesale distributor of opioids to its own free-standing Well Experience locations from these distribution centers as well.

318. At the pharmacy level, these pharmacies would have been able to observe customers, including, for example, customers with insurance coverage making cash payments. They could also identify customers filling prescriptions at multiple pharmacy branches or from different doctors, or patterns of unusual or suspicious prescribing from a particular medical provider. Moreover, CVS Health president and CEO Larry Merlo has described the company as "America's front door to health care with a presence in nearly 10,000 communities across

the country," and this position as allowing it to "see firsthand the impact of the alarming and rapidly growing epidemic of opioid addiction and misuse."

319. CVS and, upon information and belief, Walgreens, used performance metrics related to their own profits, which would rely, in part, upon the number of prescriptions dispensed. By 2010, CVS had implemented performance metrics that remain publicly available online. CVS's metrics system lacked any measurement for pharmacy accuracy or customer safety. They did, however, prioritize speed and volume, including through efforts to encourage patients to pick up initial prescriptions that might otherwise be returned to stock. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. These policies remained in place even as the epidemic raged.

320. Former pharmacists at both Walgreens and CVS alike have publically complained about pressure to put speed ahead of safety. One former Walgreens pharmacist described management critiques for "not going fast enough" in dispensing prescriptions, and believed "[t]hey'd like you to fill one a minute if you could." She recalled there was even a timer to alert her if she was falling behind, and threats of reduced hours or a move to a different store or location.[121] Concerning the metrics at CVS, one pharmacist commented that "You get stressed, and it takes your mind away from the actual prescriptions." Another former CVS pharmacist recalled that "[e]very prescription [wa]s timed," and a backlog would pop up in color on pharmacists computer screens if they fell behind.[122] Additionally, CVS has faced discrimination

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[121] *Are Business Tactics at Some Pharmacies Risking Your Health?* (Nov. 8, 2017), https://reachmd.com/news/are-business-tactics-at-some-pharmacies-risking-your-health/1610793/

[122] Sam Roe, Ray Long, and Karisa King, Contract Reporters, *Pharmacies Miss Half of Dangerous Drug Combinations*, Dec. 15, 2016,

complaints alleging that the company's "Metrics" system set unobtainable goals — or at least, goals that could not be obtained without violating the laws and practice rules governing pharmacists' professional responsibilities, edging out older pharmacists.

321. Without describing individual pharmacies, a nationally-known expert and teacher of pharmacology commented in the media that the pace and pressure of prescription quotas appeared to be having an impact on accuracy. He described data from the FDA's Adverse Event Reporting System as showing a 450% increase in reported medication errors since 2010. Anecdotally, he also "heard some pharmacists say, 'It's a blur as to what happened during the day and I can only pray I didn't make any serious mistakes.'"[123]

322. This pressure and focus on profits not only leads to mistakes, it also would necessarily deter pharmacists from carrying out their obligations to report and decline to fill suspicious orders and to exercise due care in ascertaining whether a prescription is legitimate. Indeed, a survey by the Institute for Safe Medication Practices (ISMP) revealed that 83% of the pharmacists surveyed believed that distractions due to performance metrics or measured wait times contributed to dispensing errors, as well as that 49% felt specific time measurements were a significant contributing factor."[124] In 2013, the National Association of Boards of Pharmacy (NABP), passed a resolution which cited this survey and additionally stated that "performance

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http://www.chicagotribune.com/news/watchdog/druginteractions/ct-drug-interactions-pharmacy-met-20161214-story.html

[123] ReachMd, *Are Business Tactics at Some Pharmacies Risking Your Health?* (Nov. 8, 2017), https://reachmd.com/news/are-business-tactics-at-some-pharmacies-risking-your-health/1610793/

[124] NAPB, Performance Metrics and Quotas in the Practice of Pharmacy (Resolution 109-7-13) (June 5, 2013), https://nabp.pharmacy/performance-metrics-and-quotas-in-the-practice-of-pharmacy-resolution-109-7-13/

metrics, which measure the speed and efficiency of prescription work flow by such parameters as prescription wait times, percentage of prescriptions filled within a specified time period, number of prescriptions verified, and number of immunizations given per pharmacist shift, may distract pharmacists and impair professional judgment" and "the practice of applying performance metrics or quotas to pharmacists in the practice of pharmacy may cause distractions that could potentially decrease pharmacists' ability to perform drug utilization review, interact with patients, and maintain attention to detail, which could ultimately lead to unsafe conditions in the pharmacy."[125]

323. Given this, and the additional red flags described below, Defendants should have been on notice that the diversion of opioids was likely occurring in and around Fayette County, should have investigated, ceased filling orders for opioids, and reported potential diversion to law enforcement.

324. The volume of opioids distributed in Fayette County is so high as to raise a red flag that not all of the prescriptions being ordered could be for legitimate medical uses. This is particularly true given that Fayette County's supply of opioids even exceeded statewide figures—an already high baseline given Ohio's unfortunate placement at the epicenter of the opioid crisis.

325. In addition, the crisis of fatal overdoses from prescription opioids in Ohio communities has been widely publicized for years. Fayette County, is unfortunately, among the communities hardest hit by the opioid epidemic. The County has seen a dramatic rise in fatal drug overdoses. Many of these deaths are attributable to prescription opioids, and increasingly, to illicit opiates, to which people who have become addicted to prescription opioids often transition. The

[125] *Id.*

CDC estimates that for every opioid-related death, there are 733 non-medical users. Defendants thus had every reason to believe that illegal diversion was occurring in Fayette County.

326. Not only were prescription opioids diverted within Fayette County, upon information and belief, they were being diverted into Fayette County from pill mills further south in Ohio, that, upon information and belief, these Defendants also failed to report or cease supplying. An epidemiological report from the Ohio Governor's Cabinet opiate action team cited the shutdown of southern Ohio pill mills as one of the chief factors in an increase throughout Ohio in heroin overdose rates (which, as explained below, is the drug turned to by prescription opioid users when those drugs are no longer available or too expensive). Consistent with the observed statewide trend, Fayette County has seen a spike in heroin overdoses and lives lost to synthetic opiates, such as fentanyl.

327. In addition, upon information and belief, the Defendants would have known that Ohio's crack-down on pill mills within the state did not prevent suspicious orders from being placed in the state and ultimately diverted to illicit use in Ohio communities. For example, Mallinckrodt found in November 2010 that 68% of the purchases by one of its distributors, Cincinnati-based KeySource Medical, Inc., were for prescription opioids, and that 91% of this customer's purchasers were sent to Florida.[126] During that time, Florida lacked a prescription drug monitoring program similar to Ohio, and traffickers would recruit others to travel to Florida to pick up the drugs Mallinckrodt, through wholesalers, shipped there, and bring them back to Ohio, a route that became known as the "Florida Pipeline" or "OxyContin Express."[127]

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[126] United States' Opposition to Plaintiff's Motion for a Preliminary Injunction, *KeySource Medical Inc. v. Holder*, No. 1:11-cv-00393, Doc. 9 at 6 (S.D. Ohio June 30, 2011).

[127] Decl. of DEA Diversion Investigator Christopher Kresnak, *KeySource Medical Inc. v. Holder*, No. 1:11-cv-00393, Doc. 9-2 ¶ 3 (S.D. Ohio June 30, 2011).

328. Upon information and belief, Defendants would have been aware that as Ohio cracked down on opioid suppliers, out-of-state suppliers filled the gaps, directly impacting Fayette County. Florida in particular assumed a prominent role, as its lack of regulatory oversight created a fertile ground for pill mills. Residents of other states would simply drive to Florida, stock up on pills from a pill mill, and transport them back to home to sell. The practice became so common that authorities dubbed these individuals "prescription tourists." According to the *Washington Post*, an internal summary of a federal case against Mallinckrodt, described above, showed that "Mallinckrodt's response was that 'everyone knew what was going on in Florida but they had no duty to report it.'"[128]

329. The facts surrounding numerous criminal prosecutions illustrate the common practice. For example, one man from Warren County, Ohio, sentenced to four years for transporting prescription opioids from Florida to Ohio, explained that he could get a prescription for 180 pills from a quick appointment in West Palm Beach, and that back home, people were willing to pay as much as $100 a pill—ten times the pharmacy price. In Columbus, Ohio, a DEA investigation led to the 2011 prosecution of sixteen individuals involved in the "oxycodone pipeline between Ohio and Florida."[129] When officers searched the Ohio home of the alleged leader of the group, they found thousands of prescriptions pills, including oxycodone and

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[128] The Government's Struggle to Hold Opioid Manufacturers Accountable: Sixty-six percent of all oxycodone sold in Florida came from this company. But the DEA's case against it faltered, *Washington Post*, (Apr. 2, 2017), https://www.washingtonpost.com/graphics/investigations/deamallinckrodt/?utm_term=.256b39de1578

[129] *16 charged in 'pill mill' pipeline*, Columbus Dispatch (June 7, 2011), http://www.dispatch.com/content/stories/local/2011/06/07/16-charged-in-pill-mill-pipeline.html.

hydrocodone, and $80,000 in cash. In 2015, another Columbus man was sentenced for the same conduct—paying couriers to travel to Florida and bring back thousands of prescription opioids, and, in the words of U.S. district judge Michael Watson, contributing to a "pipeline of death."[130]

330. Outside of Atlanta, Georgia, four individuals pled guilty in 2015 for operating a pill mill; the U.S. attorney's office found that most of the pain clinic's customers came from other states, including Ohio. Another investigation in Atlanta led to the 2017 conviction of two pharmacists who dispensed opioids to customers of a pill mill across from the pharmacy; many of those customers were from other states, including Ohio.

331. In yet another case, defendants who operated a pill mill in south Florida were tried in eastern Kentucky based on evidence that large numbers of customers transported oxycodone back to the area for both use and distribution by local drug trafficking organizations. As explained by the Sixth Circuit in its decision upholding the venue decision, "[d]uring its existence, the clinic generated over $10 million in profits. To earn this sum required more business than the local market alone could provide. Indeed, only about half of the PCB's customers came from Florida. Instead, the clinic grew prosperous on a flow of out-of-state traffic, with prospective patients traveling to the clinic from locations far outside Ft. Lauderdale, including from Ohio."[131]

332. The route from Florida and Georgia to Kentucky, Ohio, and West Virginia was so well traveled that it became known as the Blue Highway, a reference to the color of the 30mg oxycodone pills manufactured by Mallinckrodt.

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[130] *Leader of Ohio pill-mill trafficking scheme sentenced*, Star Beacon (July 16, 2015), http://www.starbeacon.com/news/leader-of-ohio-pill-mill-trafficking-scheme-sentenced/article_5fb058f5-deb8-5963-b936-d71c279ef17c.html.

[131] *United States v. Elliott*, 876 F.3d 855, 858 (6th Cir. 2017).

333. Based upon all of these red flags, it can be fairly inferred that Defendants had information about suspicious orders that they did not report, and also failed to exercise due diligence before filling orders from which drugs were diverted into illicit uses in Fayette County.

6. Defendants hid their lack of cooperation with law enforcement and pretended to be actively working to prevent diversion and combat the opioid epidemic

334. When a manufacturer or distributor does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action—or may not know to take action at all.

335. After being caught failing to comply with particular obligations at particular facilities, Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens. As part of McKesson's 2008 Settlement with the DEA, McKesson claimed to have "taken steps to prevent such conduct from occurring in the future," including specific measures delineated in a "Compliance Addendum" to the Settlement. Yet, in 2017, McKesson paid $150 million to resolve an investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids.

336. More generally, the Defendants publically portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that: "We challenge ourselves to best utilize our assets, expertise and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing 'the right thing' serves everyone." Defendant Cardinal likewise claims to "lead [its] industry in anti-diversion strategies to help prevent opioids

from being diverted for misuse or abuse." Along the same lines, it claims to "maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription controlled medications that do not meet [its] strict criteria." Cardinal also promotes funding it provides for "Generation Rx," which funds grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

337. Similarly, McKesson publicly claims that its "customized analytics solutions track pharmaceutical product storage, handling and dispensing in real time at every step of the supply chain process," creating the impression that McKesson uses this tracking to help prevent diversion. Its website offers assurances that the company's Controlled Substances Monitoring Program ("CSMP") "uses sophisticated algorithms designed to monitor for suspicious orders, and block the shipment of controlled substances."[132] McKesson has also publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."

338. AmerisourceBergen, too, has taken the public position that it is "work[ing] diligently to combat diversion and [is] working closely with regulatory agencies and other partners in pharmaceutical and healthcare delivery to help find solutions that will support appropriate access while limiting misuse of controlled substances." A company spokeswoman also provided assurance that: "At AmerisourceBergen, we are committed to the safe and efficient delivery of controlled substances to meet the medical needs of patients." Another AmerisourceBergen

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[132] https://www.mckesson.com/about-mckesson/fighting-opioid-abuse/pharmaceutical-supply-chain/

representative has claimed publically, on behalf of the company that, "[a]s a supply chain partner, we are committed to finding comprehensive solutions to mitigate the opioid epidemic impacting our communities, and we understand the important role we play in helping to combat medication diversion and abuse[.]"

339. Walgreens, too, publicly portrays itself as committed to working diligently to prevent diversion of these dangerous drugs and curb the opioid epidemic, including through installation of safe-disposal kits at Walgreens pharmacies and plans to make Naloxone available without a prescription, in accordance with state pharmacy regulations. Citing these efforts, Walgreens promotes itself as committed to undertaking "a comprehensive national plan announced earlier this year to address key contributors to the crisis."

340. CVS likewise claims to be "playing an active role in the search for solutions to the opioid crisis in a number of ways."

341. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, Defendants, through their trade associations, the HDMA (now HDA) and the NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:[133]

a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

b. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process."

342. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations,

[133] Brief for HDMA and NACDS, 2016 WL 1321983, at *3-4, *25.

Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

343. Mallinckrodt similarly claims to be "committed . . . to fighting opioid misuse and abuse," and further asserts that: "In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances, ..."

344. Other Marketing Defendants also misrepresented their compliance with their legal duties and their cooperation with law enforcement. Purdue serves as a hallmark example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its "constructive role in the fight against opioid abuse," including its commitment to ADF opioids and its "strong record of coordination with law enforcement."[134]

345. As described in Section G above, at the heart of Purdue's public outreach is the claim that it works hand-in-glove with law enforcement and government agencies to combat opioid abuse and diversion.

346. These public statements created the false and misleading impression that the Defendants rigorously carried out their duty to report suspicious orders and exercise due diligence to prevent diversion of these dangerous drugs, and also worked voluntarily to prevent diversion as a matter of corporate responsibility to the communities their business practices would necessarily impact.

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[134] Purdue, *Setting The Record Straight On OxyContin's FDA-Approved Label* (May 5, 2016), http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-oxycontins-fda-approved-label/; Purdue, *Setting The Record Straight On Our Anti-Diversion Programs*, (July 11, 2016) http://www.purduepharma.com/news-media/get-the-facts/setting-the-record-straight-on-our-anti-diversion-programs/.

I. BY INCREASING OPIOID PRESCRIPTIONS AND USE, DEFENDANTS COLLECTIVELY FUELED THE OPIOID EPIDEMIC AND SIGNIFICANTLY HARMED THE COUNTY AND ITS RESIDENTS.

347. Marketing Defendants' misrepresentations prompted Fayette County health care providers to prescribe and patients to take opioids for the treatment of chronic pain. Through their marketing, these Defendants overcame barriers to widespread prescribing of opioids for chronic pain with deceptive messages about the risks and benefits of long-term opioid use. Distributor Defendants compounded these harms by supplying opioids beyond even what this expanded market could bear, funneling so many opioids into Fayette County that they could only have been delivering opioids for diversion and illicit use. The massive amount of opioids that flooded into Fayette County as a result of Defendants' wrongful conduct has devastated the County and its residents.

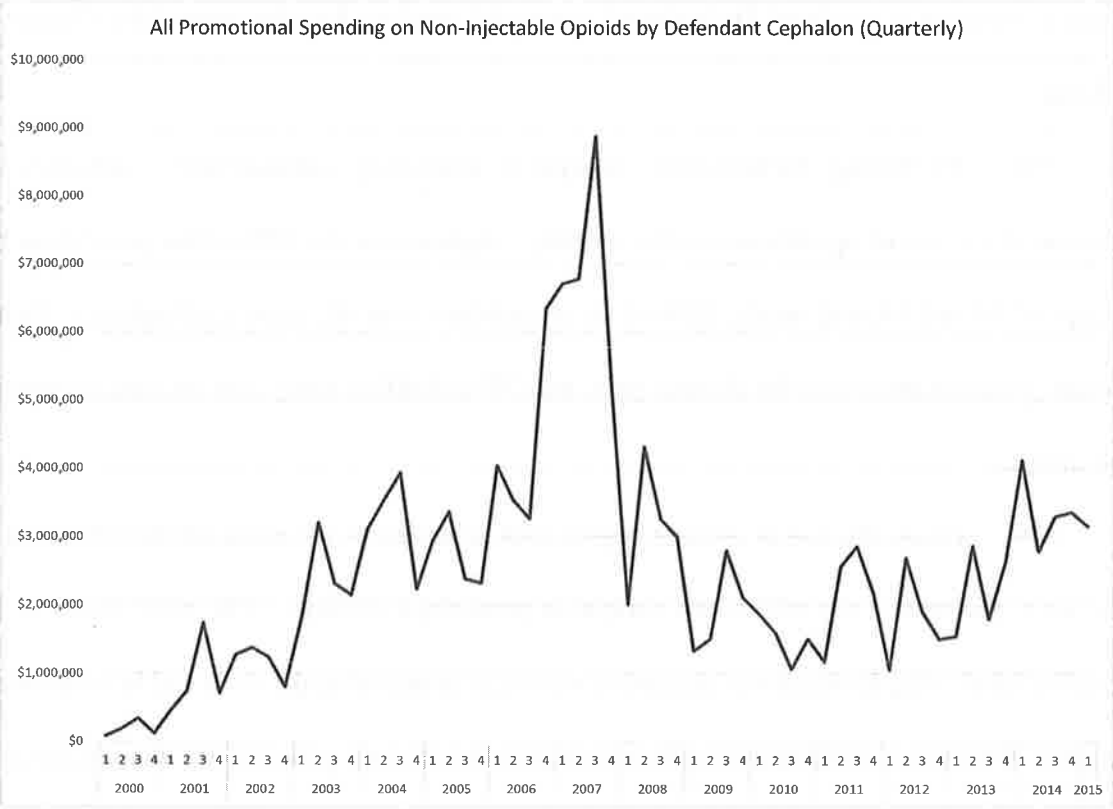
348. Marketing Defendants' deceptive marketing substantially contributed to an explosion in the use of opioids across the country. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

349. Often, the use of opioids begins with acute pain – in sports, on the job, at the dentist, or in a car accident – for which the patient is prescribed opioids. The false sense of security created by Marketing Defendants' deceptive messages concerning the risks and benefits of opioids, especially the risk of addiction, would also make doctors and patients feel more comfortable in continuing to use opioids for lingering pain needs or demands, causing some patients to become dependent and addicted.

350. Overall sales of opioids in Ohio have skyrocketed, and upon information and belief, Fayette County is no exception.

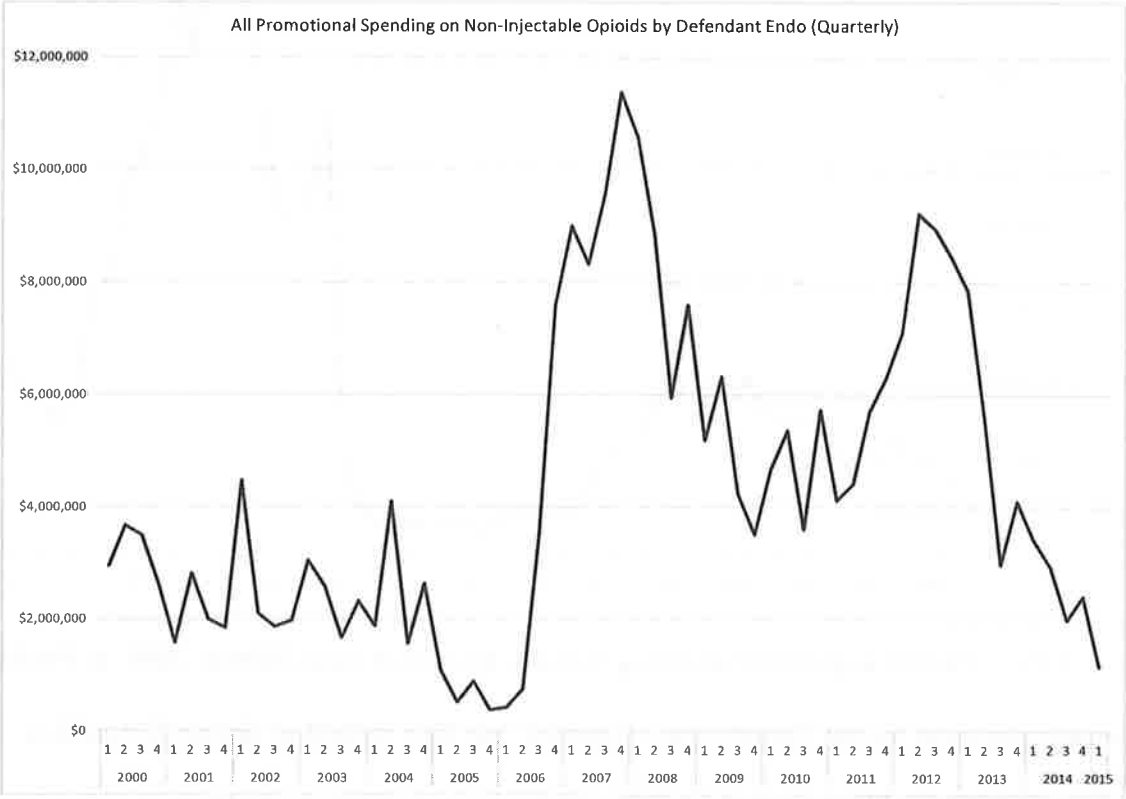
351. Marketing Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Marketing Defendants spent $166 million on detailing branded opioids to doctors. This amount is twice as much as Marketing Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Teva, and $10 million by Endo.

352. Cephalon's quarterly spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak, coinciding with the launch of Fentora, of nearly $9 million for one quarter of 2007 (and more than $27 million for the year), as shown below:

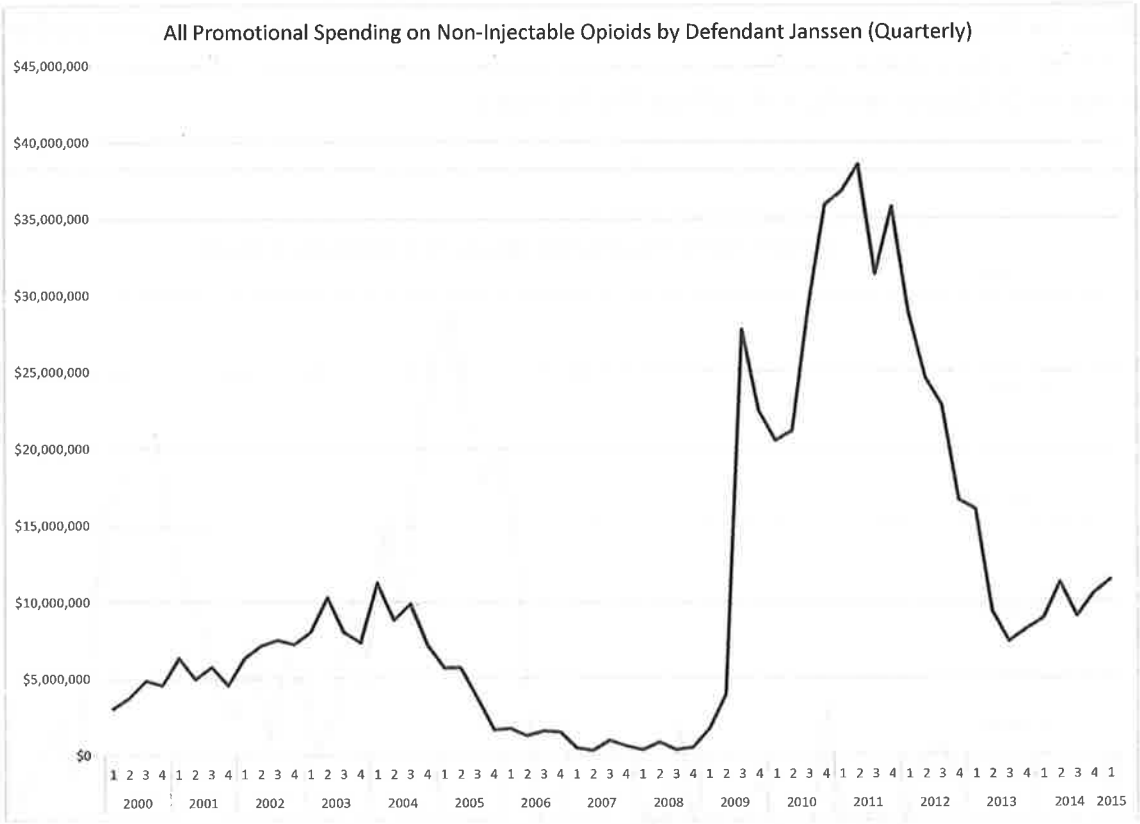


353. Endo's quarterly spending went from the $2 million to $4 million range in 2000-2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38

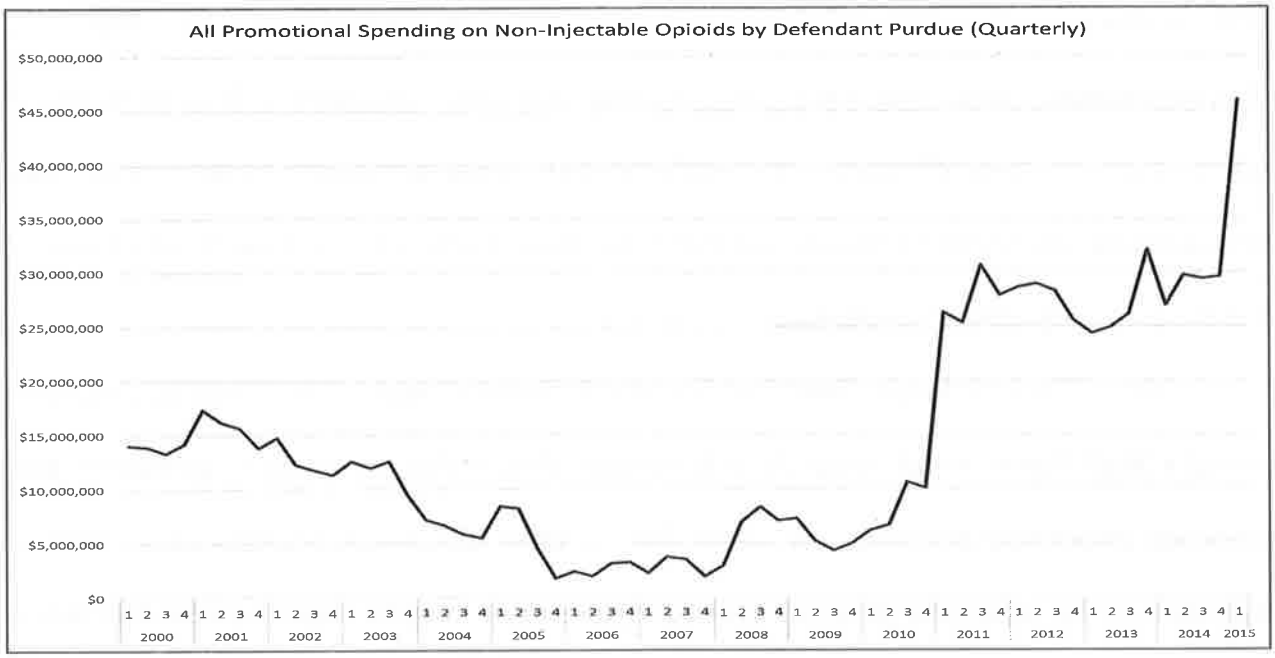
million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly $34 million for the year):



354. Janssen's quarterly spending dramatically rose from less than $5 million in 2000 to more than $30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at $142 million for 2011), as shown below:



355. Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation by the Department of Justice, but then spiked to above $25 million in 2011 (for a total of $110 million that year), and continues to rise, as shown below:



356. Marketing Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence.

357. In particular, the effects of sales calls on prescribers' behavior is well-documented in the literature, including a 2009 study correlating the nearly ten-fold increase in OxyContin prescriptions between 1997 and 2002 to Purdue's doubling of its sales force and trebling its sales calls.[135] A 2017 study found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers.[136] The changes in prescribing behavior appeared strongest at hospitals that implemented the strictest detailing policies and included enforcement measures. Another study involved the research of four

[135] Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy,* 99 Am. J. Pub. Health 221–227 (2009).

[136] Ian Larkin et al., *Association Between Academic Medical Center Pharmaceutical Detailing Policies and Physician Prescribing*, 317 J. Am. Med. Ass'n 1785 (2017).

different practices which included visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on driving drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in doctor prescribing practices and requests by physicians to add the drugs to hospitals' formularies.

358. The U.S. Senate Homeland Security & Governmental Affairs Committee recently issued a Staff Report which noted the link between drug maker payments to prescribers and physician prescribing practices. It found that "a clear link exists between even minimal manufacturer payments and physician prescribing practices."[137] The Report quotes ProPublica findings that "doctors who received industry payments were two to three times as likely to prescribe brand-name drugs at exceptionally high rates as others in their specialty."

359. The sharp increase in opioid use resulting from Marketing Defendants' conduct has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States, including in Fayette County. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."[138]

360. In August 2016, U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that

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[137] Staff Report, *Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization* at 7.

[138] "America's Addiction to Opioids: Heroin and Prescription Drug Abuse," *Senate Caucus on Int'l Narcotics Control*, hr'g, Testimony of Dr. Nora Volkow (May 14, 2014) available at http://www.drugcaucus.senate.gov/sites/default/files/Volkow%20Testimony.pdf.

crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[139]

361. Scientific evidence demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[140]

362. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[141] The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[142]

363. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[143]

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[139] *See* n.2, *supra*.

[140] Theodore J Cicero *et al.*, *Relationship Between Therapeutic Use and Abuse* of *Opioid Analgesics in Rural, Suburban, and Urban* Locations in the United States, 16.8 Pharmacoepidemiology and Drug Safety, 827-40 (2007).

[141] Dart, MD, *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, New Engl. J. Med., 372:241-248 (Jan. 15, 2015).

[142] Califf, MD, *et al.*, *A Proactive Response to Prescription Opioid Abuse,* New Engl. J. Med. (Apr. 14, 2016).

[143] CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., *et al.* "Increases in drug and opioid overdose deaths—United States, 2000–2014." American Journal of Transplantation 16.4 (2016): 1323-1327.

According to the CDC, in 2016, there were 99.2 opioid prescriptions dispersed per every 100 residents within the County.

364. By continuing to fill and failing to report suspicious orders of opioids, Distributor Defendants have enabled an oversupply of opioids, which allows non-patients to become exposed to opioids, and facilitates access to opioids for both patients who could no longer access or afford prescription opioids and addicts struggling with relapse.

365. Contrary to Defendants' misrepresentations, most of the illicit use originates from *prescribed* opioids. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.

366. Ohio's Prescription Drug Abuse Task Force similarly has found that individuals addicted to prescription opioids often transition to heroin due to its lower cost, ready availability, and similar high. Likewise, a study by the Ohio Substance Abuse Monitoring Network reported on the connection between oxycodone use and heroin addiction, finding that "[y]oung new heroin abusers seeking treatment reported OxyContin abuse prior to becoming addicted to heroin," that several reporting resorting to heroin after OxyContin became too expensive or difficult to obtain, and that "[a]buse of OxyContin prior to the abuse of heroin appears to be a common pattern."[144]

367. In fact, people who are addicted to prescription opioid painkillers are 40 times more likely to be addicted to heroin. The CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. Roughly 80% of heroin users previously used

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[144] Ohio Substance Abuse Monitoring Network, OSAM Rapid Response Investigation Reveals Connection Between OxyContin Abuse and Heroin Addiction in Some Individuals, *available* at http://mha.ohio.gov/Portals/Wassets/Learning/OSAMaan02ConnxtsOxy.pdf

or

http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwjIl6nDjZLaAhWSu1MKHXwmCMMQFggnMAA&url=http%3A%2F%2Fmha.ohio.gov%2FPortals%2F0%2Fassets%2FLearning%2FOSAM%2FJan02ConnxtsOxy.pdf&usg=AOvVaw0YQ8A4YVKePz9xajswyHMJ

prescription opioids. Similarly, Ohio's Prescription Drug Abuse Task Force has found that individuals addicted to prescription opioids often transition to heroin due to its lower cost, ready availability, and similar high.

368. A relatively recent, even more deadly problem stemming from the prescription opioid epidemic involves fentanyl—a powerful opioid prescribed for cancer pain or in hospital settings that, in synthetic form, has made its way into Ohio communities, including Fayette County. In 2016, there were six fentanyl-related deaths in County. In 2017, this number increased more than threefold to 22 deaths. In February 2017, the Fayette County Sheriff's Office issued a drug alert after there were 30 reported overdoses from fentanyl and carfentanil in the County, including one overdose at the Fayette County Jail, within a 10-day timespan. Six of these overdoses proved fatal.

369. Carfentanil as discussed above, is a powerful derivative of fentanyl, has increasingly been found in heroin and fentanyl sold illicitly. Carfentanil is so strong that it is typically used in veterinary medicine to sedate large wild animals such as elephants, and has been researched as a chemical weapon. A dose the size of a grain of salt can rapidly lead to deadly overdose in humans. Because of its potency, the Ohio Attorney General's website recommends that chemists and lab technicians who test for carfentanil use protective gear.

370. No demographic is untouched by this epidemic. Nationally, one in five deaths among younger adults in 2016 involved opioids, according to a recent study. And, deaths involving both prescription and illicit opioids have risen sharply, nearly doubling since 2009.

371. Locally, Ohio has "lead[] the country in drug overdose deaths per capita, a rate that continues to rise, overwhelming families, communities, and local governments across the state."[145] In Ohio, an average of 14 people now die, per day, from fatal drug overdoses. Provisional data from the CDC showed the crisis continuing to explode during the first half of 2017, with 5,232 Ohio overdose deaths recorded in the 12 months ending June 31, 2017. Further, even these grim numbers likely understate the number of lives lost due to incomplete reporting. From 2010 to 2015, 45 people in Fayette County lost their lives to drug overdoses. According to a statewide drug overdose report released in September 2018, Fayette County had the fifth-highest number of unintentional drug overdoses in relation to its county population in the state of Ohio.

372. Opioid addiction and misuse also result in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of Narcan or naloxone—the antidote to opioid overdose. Once addicted, people working to recover may struggle with their addiction their entire lives.

373. Opioid addiction is now the primary reason that Ohioans seek substance abuse treatment. In 2014, 37% of admissions for drug abuse were associated with a primary diagnosis of opioid abuse or dependence. According to a 2015 poll, 3 in 10 Ohio adults have family members or friends who have experienced problems as a result of abusing prescription pain relievers, a steep rise from only a year earlier, and 2 in 10 Ohio adults had family or friends whom they described as experiencing problems from using heroin. Of these Ohioans, 4 in 10 knew someone who had overdosed due to a pain drug, and 6 in 10 knew someone who had overdosed on heroin.

[145] C. William Swank Program in Rural-Urban Policy, Taking Measure of Ohio's Opioid Crisis, The Ohio State University (Oct. 2017) at 1.

374. Opioids have caused injury and illness in Fayette County in other respects as well. An increase in Hepatitis C, according to the CDC, is directly tied to intravenous injection of opioids. The number of cases of chronic Hepatitis C in Ohio nearly tripled from 2011-2015, an increase that resulted largely from intravenous use of drugs, including OxyContin and other prescription painkillers, stemming from the opioid epidemic. The co-morbidity is sufficiently high that the Ohio Department of Health recommends that women of childbearing age who have tested positive for drug and dependence also receive screening for Hepatitis C and HIV.

375. The deceptive marketing, overprescribing, and oversupply of opioids also had a significant detrimental impact on children. Young children have access to opioids, nearly all of which were prescribed or supplied to adults in their household. If parents become addicted and turn to illicit opiates, children risk overdose from these drugs as well. One counselor in the County noted that syringes were found in a bathroom at the high school.

376. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction. When untreated, NAS can be life-threatening. In 2009, more than 13,000 infants in the United States were born with NAS, or about one every hour.

377. In Ohio, the number of infants born with NAS increased six-fold in from 2004 to 2011. From 2009 to 2014, data from seven regional hospitals showed a greater-than six-fold increased in drug-exposed infants. As a whole, the State has seen an 816% increase in the number of infants born with NAS from 2006 to 2015, with opioids and other illegal narcotics being the most commonly implicated drugs since 2009. In 2015 alone, 2,174 infants were admitted to inpatient settings for this painful condition, an average of six per day. NAS has become so prevalent in Ohio Communities that the state's Department of Health now recommends screening all newborns for this condition.

378. This dramatic rise in NAS may be described as an epidemic within an epidemic. According to the Ohio Perinatal Quality Collaborative, the "NAS epidemic is steadily increasing, overwhelming social service systems and public payers."[146] In 2013, the average inpatient stay and bill for babies suffering from NAS was four times longer and four times higher than for other infants in Ohio. Newborns with NAS spent approximately 26,000 days in Ohio hospitals in 2014, with health care costs totaling $105 million. Ohio's healthcare system alone has contributed more than $133 million to NAS-related hospital charges in 2015. From 2011 to 2015, 30 newborns were hospitalized due to NAS in Fayette County, and there were 17.9 cases of NAS for every 1,000 live births.

379. Further, "[c]hildren of parents addicted to opiates," have been described as the "invisible victims of the epidemic," are "flooding into the state's child protection system."[147] Statewide, the opioid epidemic is largely responsible for the 9% increase in the numbers of children

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[146] Neonatal Abstinence Syndrome Project, OPQC, Ohio Perinatal Quality Collaborative, *available at* https://opqc.net/projects/NAS.

[147] Public Children Services Association of Ohio (PCSAO), http://www.pcsao.org/programs/opiate-epidemic

- nearly 1,100 – placed in the care of Ohio child protection agencies between 2011 and 2015.[148] Seventy percent of infants placed in Ohio's foster care system are children of parents with opioid addictions. Further, these figures do not account for children who are placed in kinship care or who receive public services without being displaced from their homes.

380. In Ohio, there has been a 62% increase in the number of children placed in a relative's care between 2011 and 2016. As of May 2017, approximately 124,000 children – 5% of the children in the state, were being raised by relatives other than their parents.

381. Children removed from homes with drug abuse tend to stay in foster care longer and to enter foster care having experienced more significant trauma, which makes their care more expensive. Many of these kids watched their parents overdose or die," according to the executive director of the Public Children Services Association of Ohio ("PCSAO"), a statewide membership organization for county children services agencies.[149] Children may have gone days without food or supervision, and older children may have functioned as surrogate parents to their younger siblings, reported Ohio's Attorney General in 2017.[150] Early last year, a five-year-old child watched as her mother, along with her mother's boyfriend, overdosed on heroin at their home. Looking for help, she dialed random numbers until she reached a family friend, who called 911. Paramedics revived the couple, and less than two weeks later, the mother overdosed again.

382. A statewide report found that increasingly, children entering the foster care system from homes with drug abuse are dealing with significant mental health issues, requiring intensive

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[148] Public Children Services Association of Ohio, Ohio's Opiate Epidemic and Child Protection (2016), *available at* http://www.pcsao.orepdf/advocacy/PCSA0OpiateEpidemicChildProtectionBrief2016.pdf.

[149] Chris Stewart, *Foster Care Report: 'Many of these kids watched their parents overdose or die,'* Dayton Daily News, available at https://www.mydaytondailynews.com/news/foster-care-report-many-these-kids-watched-their-parents-overdose-die/X4ytHHs6IlO5D8GseUQclK/; http://www.pcsao.org/programs/opiate-epidemic

[150] *Id.*

treatment that may cost as much as $200 to $400 a day, because of what they have seen or experienced. Ohio has the heaviest reliance on local dollars for child protection services of any state in the nation, with counties shouldering more than half of the costs through local government funds and/or dedicated levies.

383. The number of children in foster care in the County has more than doubled in the last five years. In 2013, there were 29 children in foster care, and as of March 2017, there were 63 children in foster care in the County. That increase is attributable to the opioid epidemic. According to the County's Department of Job and Family Services, "[t]he cases are more complex, we're with them longer. Children are in care a lot longer as parents go through treatment getting clean."[151] Fayette County's Children Services has similarly reported the increase in foster care is "very much driven by the opioid and heroin epidemic."[152] Overall, about 70% of the children in foster care in the County have been placed in the County's care due to the opioid epidemic.

384. With that increase, the Fayette County Department of Job and Family Services has recently seen a 179% increase in the cost of foster care. In January 2017 alone, the agency spent $67,890.48 on foster care. Making the situation more difficult, there are not enough homes in the County to take in all the children being displaced from theirs. The County has worked to find homes in other parts of the state, allowing children to stay in the area that is familiar for them. Caseworkers from the County continue to make home visits in these distant homes, driving as many as six hours across the state to do so. This distance increases the cost to the County and strain the agency's budget and human resources as the County works to provide these services.

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[151] Ashley Bunton, *Opioid Epidemic Has Doubled the Number of Kids in Foster Care*, Record Herald (Mar. 15, 2017), https://www.recordherald.com/news/13235/opioid-epidemic-has-doubled-the-number-of-kids-in-foster-care

[152] *Id.*

385. Rising opioid use and abuse have negative social and economic consequences far beyond overdoses in other respects as well. According to a recent analysis by a Princeton University economist, approximately one out of every three working-age men who are not in the labor force take daily prescription pain medication. The same research finds that opioid prescribing alone accounts for 20% of the overall decline in the labor force participation for this group from 2014-16, and 25% of the decline in labor force participation among women. Many of those taking painkillers still said they experienced pain daily. A recent report by The Ohio State University estimated that in Ohio, in 2015 alone, "opioid overdoses resulted in $3.8 billion in lost lifetime productivity" and "[i]n total, the cost of opioid abuse and dependency ranged from $6.6 billion to $8.8 billion."[153]

386. The County seeks to reach people in need of help through a new program called Project DAWN (Deaths Avoided with Naloxone). Project Dawn is an overdose education and naloxone distribution program. In the program, participants learn how to recognize the symptoms and signs of an opioid overdose, make an emergency 911 call, perform rescue breathing, and administer Narcan. In August 2017, DAWN was awarded $1 million by the Ohio Department of Health to expand the availability of Narcan.

387. The County's Health Department runs a needle exchange program that offers clean needles and HIV testing to an average of 160 people in a window of less than five hours each week. The program previously providing naloxone kits as well, and continued to receive weekly requests, but had no funding to continue to provide this life-saving tool.

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[153] C. William Swank Program in Rural-Urban Policy, Taking Measure of Ohio's Opioid Crisis, The Ohio State University (Oct. 2017) at 8.

388. As a result of the impacts described above, and others, the County has incurred substantial expense to address the opioid epidemic created by Defendants' misconduct.

J. STATUTES OF LIMITATIONS ARE TOLLED AND DEFENDANTS ARE ESTOPPED FROM ASSERTING STATUTES OF LIMITATIONS AS DEFENSES.

A. Continuing Conduct

368. The County continues to suffer harm from Defendants' unlawful actions.

369. The continued tortious and unlawful conduct by Defendants causes a repeated or continuous injury. The damages have not occurred all at once but have continued to occur and have increased as time progresses. The tort is not completed nor have all the damages been incurred until the wrongdoing ceases. Defendants' wrongdoing and unlawful activity has not ceased. The public nuisance remains unabated, as does the conduct causing the nuisance.

B. Equitable Estoppel and Fraudulent Concealment

370. Defendants are equitably estopped from relying upon a statute of limitations defense because they undertook active efforts to deceive the County and to purposefully conceal their unlawful conduct and fraudulently assure the public, including state and local governments, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered distributor status in Ohio and continuing to generate profits. Notwithstanding the allegations set forth above, Defendants affirmatively assured the public, and state and local governments, that they are working to curb the opioid epidemic.

371. Defendants were deliberate in taking steps to conceal their conspiratorial behavior and active role in the oversupply of opioids, which fueled the opioid epidemic.

372. As set forth herein, Defendants concealed from the County the existence of the County's claims by hiding their lack of cooperation with law enforcement and affirmatively

seeking to convince the public that their legal duties to report suspicious sales had been satisfied through public assurances that they were working to curb the opioid epidemic. They publicly portrayed themselves as committed to working diligently with law enforcement and others to prevent diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises to change their ways insisting they were good corporate citizens. These repeated misrepresentations misled regulators, prescribers and the public, including the County, and deprived the County of actual or implied knowledge of facts sufficient to put the County on notice of potential claims.

373. The County did not discover the nature, scope, and magnitude of Defendants' misconduct, and its full impact on the County, and the County could not have acquired such knowledge earlier through the exercise of reasonable diligence.

374. Further, Defendants have also concealed and prevented discovery of information that will confirm their identities and the extent of their wrongful and illegal activities.

375. Defendants made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing, including marketing by third parties they sponsored, was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Defendants of this, and likewise, Purdue and Teva paid hundreds of millions of dollars to address similar misconduct that occurred before 2008. Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More

recently, the FDA and CDC have issued pronouncements based on existing medical evidence that conclusively exposes the known falsity of Defendants' misrepresentations.

376. Notwithstanding this knowledge, at all times relevant to this Complaint, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful and fraudulent conduct. Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through biased science, unbranded marketing, third-party advocates, and professional associations. Defendants purposefully hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of their false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Purdue, Endo, Teva, and Janssen, masked or never disclosed their role in shaping, editing, and approving the content of this information.

377. Defendants thus successfully concealed from the medical community, patients, and the County facts sufficient to arouse suspicion of the claims that the County now asserts. The County did not know of the existence or scope of Defendants' fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

K. FACTS PERTAINING TO CLAIMS UNDER THE OHIO CORRUPT PRACTICES ACT ("OCPA")

A. The Opioid Marketing Enterprise

1. The Common Purpose and Scheme of the Opioid Marketing Enterprise

378. Knowing that their products were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain, the Marketing Defendants formed an association-in-fact enterprise and engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through repeated and

systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain.

389. In order to unlawfully increase the demand for opioids, the Marketing Defendants formed an association-in-fact enterprise (the "Opioid Marketing Enterprise") with the "Front Groups" and KOLs described above. Through their personal relationships, the members of the Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the Opioid Marketing Enterprise's common purpose. The Marketing Defendants' substantial financial contribution to the Opioid Marketing Enterprise, and the advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.

390. The Marketing Defendants, through the Opioid Marketing Enterprise, concealed the true risks and dangers of opioids from the medical community and the public, including the County, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. The misleading statements included: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition the Marketing Defendants named "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing present no significant risks; (6) that long-term use of opioids improves function; and (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids.

391. The scheme devised, implemented and conducted by the Marketing Defendants was a common course of conduct designed to ensure that the Marketing Defendants unlawfully increased their sales and profits through concealment and misrepresentations about the addictive nature and effective use of the Marketing Defendants' drugs. The Marketing Defendants, the Front

Groups, and the KOLs acted together for a common purpose and perpetuated the Opioid Marketing Enterprise's scheme, including through the unbranded promotion and marketing network as described above.

392. There was regular communication between the Marketing Defendants, Front Groups and KOLs, in which information was shared, misrepresentations were coordinated, and payments were exchanged. Upon information and belief, typically, the coordination, communication and payment occurred, and continues to occur, through the repeated and continuing use of the wires and mail in which the Marketing Defendants, Front Groups, and KOLs share information regarding overcoming objections and resistance to the use of opioids for chronic pain. The Marketing Defendants, Front Groups and KOLs functioned as a continuing unit for the purpose of implementing the Opioid Marketing Enterprise's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.

393. At all relevant times, the Front Groups were aware of the Marketing Defendants' conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the County. But for the Opioid Marketing Enterprise's unlawful fraud, the Front Groups would have had incentive to disclose the deceit by the Marketing Defendants and the Opioid Marketing Enterprise to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

394. At all relevant times, the KOLs were aware of the Marketing Defendants' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct. The Marketing Defendants selected KOLs solely because they favored the aggressive treatment of

chronic pain with opioids. The Marketing Defendants' support helped the KOLs become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the benefits of using opioids to treat chronic pain, repaying the Marketing Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLS and Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the County. But for the Opioid Marketing Enterprise's unlawful conduct, the KOLs would have had incentive to disclose the deceit by the Marketing Defendants and the Opioid Marketing Enterprise, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs furthered the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

395. As public scrutiny and media coverage focused on how opioids ravaged communities in Ohio and throughout the United States, the Front Groups and KOLS did not challenge the Marketing Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioid Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence.

396. The Marketing Defendants, Front Groups and KOLs engaged in certain discrete categories of activities in furtherance of the common purpose of the Opioid Marketing Enterprise. As described herein, the Opioid Marketing Enterprise's conduct in furtherance of the common purpose of the Opioid Marketing Enterprise involved: (1) misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term chronic pain (described in detail above); (2) lobbying to defeat measures to restrict over-prescription; (3) efforts to criticize or undermine CDC guidelines; and (4) efforts to limit prescriber accountability.

397. In addition to disseminating misrepresentations about the risks and benefits of opioids, the Opioid Marketing Enterprise also furthered its common purpose by criticizing or undermining CDC Guideline. Members of the Opioid Marketing Enterprise criticized or undermined the CDC Guideline, which represented "an important step—and perhaps the first major step from the federal government—toward limiting opioid prescriptions for chronic pain."

398. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized the draft guidelines in 2015, arguing that the "CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest of the individuals who participated in the construction of these guidelines."

399. The AAPM criticized the prescribing guidelines in 2016, through its immediate past president, stating "that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence."

400. The Marketing Defendants alone could not have accomplished the purpose of the Opioid Marketing Enterprise without the assistance of the Front Groups and KOLs, who were perceived as "neutral" and more "scientific" than the Marketing Defendants themselves. Without the work of the Front Groups and KOLs in spreading misrepresentations about opioids, the Opioid Marketing Enterprise could not have achieved its common purpose.

401. The impact of the Opioid Marketing Enterprise's scheme is still in place—*i.e.*, the opioids continue to be prescribed and used for chronic pain throughout the area of Fayette County and the epidemic continues to injure the County, and consume the resources of the County's health care and law enforcement systems.

402. As a result, it is clear that the Marketing Defendants, the Front Groups, and the KOLs were each willing participants in the Opioid Marketing Enterprise, had a common purpose

and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

2. The Conduct of the Opioid Marketing Enterprise violated OCPA

403. From approximately the late 1990s to the present, each of the Marketing Defendants exerted control over the Opioid Marketing Enterprise and participated in the operation or management of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. Creating and providing a body of deceptive, misleading and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians and patients;

b. Creating and providing a body of deceptive, misleading and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians and patients;

c. Creating and providing a body of deceptive, misleading and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians and patients;

d. Creating and providing a body of deceptive, misleading and unsupported CMEs and speaker presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians and patients;

e. Selecting, cultivating, promoting and paying KOLs based solely on their willingness to communicate and distribute the Marketing Defendants' messages about the use of opioids for chronic pain;

f. Providing substantial opportunities for KOLs to participate in research studies on topics the Marketing Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

g. Paying KOLs to serve as consultants or on the Marketing Defendants' advisory boards, on the advisory boards and in leadership positions on Front Groups, and to give talks or present CMEs, typically over meals or at conferences;

h. Selecting, cultivating, promoting, creating and paying Front Groups based solely on their willingness to communicate and distribute the Marketing Defendants' messages about the use of opioids for chronic pain;

i. Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics the Marketing Defendants suggested or chose (and paid for), with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

j. Paying significant amounts of money to the leaders and individuals associated with Front Groups;

k. Donating to Front Groups to support talks or CMEs, that were typically presented over meals or at conferences;

l. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

m. Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;

n. Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and the help of the Front Groups as publishers, and supporters;

o. Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the Marketing Defendants, such as the elderly, and then funding that distribution;

p. Concealing their relationship to and control of Front Groups and KOLs from the County and the public at large; and

q. Intending that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

404. The Opioid Marketing Enterprise had a hierarchical decision-making structure that was headed by the Marketing Defendants and corroborated by the KOLs and Front Groups. The Marketing Defendants controlled representations made about their opioids and their drugs, doled out funds to PBMs and payments to KOLs, and ensured that representations made by KOLs, Front

Groups, and the Marketing Defendants' sales detailers were consistent with the Marketing Defendants' messaging throughout the United States and Ohio. The Front Groups and KOLS in the Opioid Marketing Enterprise were dependent on the Marketing Defendants for their financial structure and for career development and promotion opportunities.

405. The Front Groups also conducted and participated in the conduct of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The Front Groups promised to, and did, make representations regarding opioids and the Marketing Defendants' drugs that were consistent with the Marketing Defendants' messages;

b. The Front Groups distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

c. The Front Groups echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the Marketing Defendants;

d. The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The Front Groups strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and

f. The Front Groups concealed their connections to the KOLs and the Marketing Defendants.

406. The Marketing Defendants' Front Groups, "with their large numbers and credibility with policymakers and the public—have 'extensive influence in specific disease areas.'" The larger Front Groups "likely have a substantial effect on policies relevant to their industry sponsors."[154] "By aligning medical culture with industry goals in this way, many of the groups

[154] U.S. Senate Homeland Security & Governmental Affairs Committee, *Fueling an Epidemic: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy*

described in this report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic."[155]

407. The KOLs also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The KOLs promised to, and did, make representations regarding opioids and the Marketing Defendants' drugs that were consistent with the Marketing Defendants' messages themselves;

b. The KOLs distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

c. The KOLs echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of the Marketing Defendants;

d. The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;

e. The KOLs strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and

f. The KOLs concealed their connections to the Front Groups and the Marketing Defendants, and their sponsorship by the Marketing Defendants.

408. The scheme devised and implemented by the Marketing Defendants and members of the Opioid Marketing Enterprise, amounted to a common course of conduct intended to increase the Marketing Defendants' sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

Groups, (February 12, 2018) https://www.hsdl.org/?abstract&did=808171 ("*Fueling an Epidemic*"), at 1.

[155] *Id.* at 2.

3. The Marketing Defendants Controlled and Paid Front Groups and KOLs to Promote and Maximize Opioid Use

409. As discussed in detail above, the Marketing Defendants funded and controlled the various Front Groups, including APF, AAPM/APS, FSMB, Alliance for Patient Access, USPF, and AGS. The Front Groups, which appeared to be independent, but were not, transmitted the Marketing Defendants' misrepresentations. The Marketing Defendants and the Front Groups thus worked together to promote the goals of the Opioid Marketing Enterprise.

410. The Marketing Defendants worked together with each other through the Front Groups that they jointly funded and through which they collaborated on the joint promotional materials described above.

411. Similarly, as discussed in detail above, the Marketing Defendants paid KOLs, including Drs. Russell Portenoy, Perrry Fine, Scott Fishman, and Lynn Webster, to spread their misrepresentations and promote their products. The Marketing Defendants and the KOLs thus worked together to promote the goals of the Opioid Marketing Enterprise.

4. Pattern of Corrupt Activity

412. The Marketing Defendants' scheme described herein was perpetrated, in part, through multiple acts of mail, wire, and telecommunications fraud constituting a pattern of racketeering activity as described herein.

413. The pattern of corrupt activity used by the Marketing Defendants and the Opioid Marketing Enterprise likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities, and of wire, radio, satellite, telecommunication, telecommunications devices or services, in furtherance of the unlawful Opioid Marketing Enterprise, including essentially uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and

non-cancer pain, with the goal of profiting from increased sales of the Marketing Defendants' drugs induced by consumers, prescribers, regulators and the County's reliance on the Marketing Defendants' misrepresentations.

414. Each of these fraudulent mailings and interstate wire transmissions constitutes corrupt activity and collectively, these violations constitute a pattern of corrupt activity, through which the Marketing Defendants, the Front Groups and the KOLs defrauded and intended to defraud Ohio consumers, the State, and other intended victims.

415. The Marketing Defendants devised and knowingly carried out an illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive and effective use of opioids for long-term chronic, non-acute and non-cancer pain. The Marketing Defendants and members of the Opioid Marketing Enterprise knew that these representations violated the FDA approved use these drugs, and were not supported by actual evidence. The Marketing Defendants intended that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate wire facilities, intentionally and knowingly with the specific intent to advance, and for the purpose of executing, their illegal scheme.

416. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain to prescribers, regulators and the public, including the County, the Marketing Defendants, the Front Groups and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of corrupt activity.

417. The Marketing Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands of communications, publications, representations, statements, electronic transmissions, payments, including, *inter alia*:

a. Marketing materials about opioids, and their risks and benefits, which the Marketing Defendants sent to health care providers, transmitted through the internet and television, published, and transmitted to Front Groups and KOLs located across the country and the State;

b. Written representations and telephone calls between the Marketing Defendants and Front Groups regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;

c. Written representations and telephone calls between the Marketing Defendants and KOLs regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;

d. E-mails, telephone and written communications between the Marketing Defendants and the Front Groups agreeing to or implementing the opioids marketing scheme;

e. E-mails, telephone and written communications between the Marketing Defendants and the KOLs agreeing to or implementing the opioids marketing scheme;

f. Communications between the Marketing Defendants, Front Groups and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

g. Communications between the Marketing Defendants, KOLs and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

h. Written and oral communications directed to State agencies, federal and state courts, and private insurers throughout the State that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and

i. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities—the wrongful proceeds of the scheme.

418. In addition to the above-referenced predicate acts, it was intended by and foreseeable to the Marketing Defendants that the Front Groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities, and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

419. To achieve the common goal and purpose of the Opioid Marketing Enterprise, the Marketing Defendants and members of the Opioid Marketing Enterprise hid from the consumers, prescribers, regulators and the the County: (a) the fraudulent nature of the Marketing Defendants' marketing scheme; (b) the fraudulent nature of statements made by the Marketing Defendants and by their KOLs, Front Groups and other third parties regarding the risks and benefits of prescription opioids; and (c) the true nature of the relationship between the members of the Opioid Marketing Enterprise.

420. The Marketing Defendants, and each member of the Opioid Marketing Enterprise agreed, with knowledge and intent, to the overall objective of the Marketing Defendants' fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in marketing prescription opioids.

421. Indeed, for the Marketing Defendants' fraudulent scheme to work, each of them had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that the Marketing Defendants each financed, supported, and worked through the same KOLs and Front Groups, and often collaborated on and mutually supported the same publications, CMEs, presentations, and prescription guidelines

422. The Marketing Defendants' predicate acts all had the purpose of creating the opioid epidemic that substantially injured the County's business and property, while simultaneously generating billion-dollar revenue and profits for the Marketing Defendants. The predicate acts were committed or caused to be committed by the Marketing Defendants through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent scheme.

B. <u>The Opioid Supply Chain Enterprise</u>

423. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resort to "a categorical denial of any

criminal behavior or intent."[156] Defendants' actions went far beyond what could be considered ordinary business conduct. For more than a decade, Defendants Purdue, Teva, Endo, Mallinckrodt, AmerisourceBergen, Cardinal, and McKesson (the "Supply Chain Defendants") worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.

424. As explained above, Ohio statutes and regulations, as well as the federal CSA and its implementing regulations require that companies who are entrusted with permission to operate within the closed system of opioid distribution cannot simply operate as competitive in an "anything goes" profit-maximizing market. Instead, they must watch over themselves and each other with a careful eye for suspicious activity. Driven by greed, Defendants betrayed that trust and subverted the constraints of these laws and the closed system to conduct their own enterprise for evil.

425. As "registrants" under the CSA, the Supply Chain Defendants are duty bound to identify and report "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[157] Ohio law imposes requirements that are no less stringent.

426. If morality and the law did not suffice, competition dictates that the Supply Chain Defendants would turn in their rivals when they had reason to suspect suspicious activity. Indeed, if a company could gain market share by reporting a competitor's illegal behavior (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so. Unfortunately, however, that is not what happened. Instead, knowing that

[156] http://www.mckesson.com/about-mckesson/fighting-opioid-abuse/60-minutes-response

[157] 21 C.F.R. 1301.74(b).

investigations into potential diversion would only lead to shrinking markets, Defendants elected to operate in a conspiracy of silence, in violation of both the CSA and Ohio law, including the Ohio Corrupt Practices Act ("OCPA").

427. The Supply Chain Defendants' scheme required the participation of all. If any one member broke rank, its compliance activities would highlight deficiencies of the others, and their artificially high sales they maintained through their scheme would crumble. But, if all the members of the enterprise conducted themselves in the same manner, it would be difficult for the DEA to go after any one of them. Accordingly, through the connections they made as a result of their participation in the Healthcare Distribution Alliance ("HDA"), the Supply Chain Defendants chose to flout the closed system designed to protect the citizens. Publicly, in 2008, they announced their formulation of "Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances." But, privately, Defendants refused to act and through their lobbying efforts, they collectively sought to undermine the impact of the CSA. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize these Defendants' duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Yet, the Supply Chain Defendants apparently all found the same profit-maximizing balance -- intentionally remaining silent to ensure the largest possible financial return.

428. As described above, at all relevant times, the Supply Chain Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues,

and profits through a fraudulent scheme that would allow them to collectively benefit from a greater pool of prescription opioids to distribute. In support of this common purpose and fraudulent scheme, the Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease in profits and sales.

429. At all relevant times, as described above, the Supply Chain Defendants exerted control over, conducted and/or participated in the Opioid Supply Chain Enterprise by fraudulently claiming that they were complying with their duties under the CSA to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to increase sales and generate unlawful profits, as follows:

430. The Supply Chain Defendants disseminated false and misleading statements to state and federal regulators claiming that:

a. they were complying with their obligations to maintain effective controls against diversion of their prescription opioids;

b. they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;

c. they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids; and

d. they did not have the capability to identify suspicious orders of controlled substances or were in the midst of a learning curve.

431. The Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress

to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[158]

432. The CSA and the Code of Federal Regulations, require the Supply Chain Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make reports as required by the CSA and Code of Federal Regulations amounts to a criminal violation of the statute.

433. The Supply Chain Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other documents required to be filed with the DEA. Specifically, the Supply Chain Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports.

434. The Supply Chain Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements under state and federal law and the actions necessary to

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[158] *See HDMA is now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

435. In devising and executing the illegal scheme, the Supply Chain Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

436. For the purpose of executing the illegal scheme, the Supply Chain Defendants committed incidents of corrupt activity, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme. These incidents of corrupt activity, which included repeated acts of mail fraud, wire fraud, and telecommunications fraud, constituted a pattern of corrupt activity.

437. The Supply Chain Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Distributor Defendants or third parties that were foreseeably caused to be sent as a result of the Defendants' illegal scheme, including but not limited to:

a. The prescription opioids themselves;

b. Documents and communications that facilitated the purchase and sale of prescription opioids;

c. Supply Chain Defendants' DEA registrations and state registrations or licenses;

d. Documents and communications that supported and/or facilitated Supply Chain Defendants' DEA registrations and state licenses or registrations;

e. Supply Chain Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827 and Ohio law;

f. Documents and communications related to the Supply Chain Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74 and Ohio law;

g. Documents intended to facilitate the distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;

h. Documents for processing and receiving payment for prescription opioids;

i. Payments from the Distributor Defendants to the Marketing Defendants;

j. Rebates and chargebacks from the Marketing Defendants to the Distributor Defendants;

k. Payments to the Supply Chain Defendants' lobbyists through the PCF;

l. Payments to the Supply Chain Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

m. Deposits of proceeds from the Supply Chain Defendants' distribution of prescription opioids; and

n. Other documents and things, including electronic communications.

438. Each of the Supply Chain Defendants identified shipped, paid for and received payment for the drugs identified above, *see* paragraphs throughout the United States.

439. The Supply Chain Defendants used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the Supply Chain Defendants made misrepresentations about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

440. At the same time, the Supply Chain Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

441. The Supply Chain Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

442. The Supply Chain Defendants also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail with each other and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

443. The mail and wire transmissions described herein were made in furtherance of the Supply Chain Defendants' scheme and common course of conduct to deceive regulators, the public and the County that these Defendants were complying with their state and federal obligations to identify, halt, and report suspicious orders of prescription opioids all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The Supply Chain Defendants' scheme and common course of conduct was to increase or maintain artificially high sales for their prescription opioids from which they could profit.

444. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden by Defendants and cannot be alleged without access to Defendants' books and records. However, the County has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

445. The Supply Chain Defendants did not undertake the practices described herein in isolation, but as part of a common scheme.

446. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly

addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

447. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured the County's business and property, while simultaneously generating billion-dollar revenue and profits for the Supply Chain Defendants. The predicate acts were committed or caused to be committed by the Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

448. As described above, the Supply Chain Defendants were repeatedly warned, fined, and found to be in violation of applicable law and regulations, and yet they persisted. The sheer volume of enforcement actions against the Supply Chain Defendants supports this conclusion that the Supply Chain Defendants operated through a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74.

449. Each instance of corrupt activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, Fayette County, and its residents. The Supply Chain Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on the County and its residents. The Supply Chain Defendants were aware that the County and its residents rely on these Defendants to maintain a closed system of distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

450. By intentionally refusing to report and halt suspicious orders of their prescription opioids, the Supply Chain Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of corrupt activity.

CAUSES OF ACTION

COUNT I
Statutory Public Nuisance
(Against All Defendants)
(Brought by the County of Fayette and The State of Ohio ex rel. Jess Weade the County Prosecutor of Fayette County, each as the Plaintiff in this Count)

451. The County incorporates the allegations within all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

452. The Prosecuting Attorney for Fayette County, Jess Weade, brings this claim in the name of the State of Ohio pursuant to the statutory authority granted under R.C. § 3767.03, to abate a public nuisance and to enjoin further maintenance of the nuisance. R.C. § 3767.03 provides: "Whenever a nuisance exists the attorney general; the village solicitor, city director of law, or other similar chief legal officer of the municipal corporation in which the nuisance exists; the prosecuting attorney of the County in which the nuisance exists; the law director of a township that has adopted a limited home rule government under Chapter 504. of the Revised Code; or any person who is a citizen of the County in which the nuisance exists may bring an action in equity in the name of the state, upon the relation of the attorney general; the village solicitor, city director of law, or other similar chief legal officer of the municipal corporation; the prosecuting attorney; the township law director; or the person, to abate the nuisance and to perpetually enjoin the person maintaining the nuisance from further maintaining it."

453. The Prosecuting Attorney for Fayette County also brings this claim in the name of the State of Ohio pursuant to the statutory authority granted under R.C. § 4729.35 to enjoin a violation of that statute.

454. Ohio statutory law provides that "[a]s used in all sections of the Revised Code relating to nuisances . . . (C) "Nuisance" means any of the following: . . . (1) [t]hat which is defined and declared by statutes to be a nuisance . . . ." R.C. § 3767.01.

455. Ohio statutory law "declare[s] to be inimical, harmful, and adverse to the public welfare of the citizens of Ohio and to constitute a public nuisance" "[t]he violation by a pharmacist or other person of any laws of Ohio or of the United States of America or of any rule of the board of pharmacy controlling the distribution of a drug of abuse as defined in section 3719.011 of the Revised Code . . . ." R.C. § 4729.35.

456. Opioids are "a drug of abuse" as defined in R.C. § 3719.011.

457. Under R.C. § 3767.02, "Any person, who uses, occupies, establishes, or conducts a nuisance, or aids or abets in the use, occupancy, establishment, or conduct of a nuisance; the owner, agent, or lessee of an interest in any such nuisance; any person who is employed in that nuisance by that owner, agent, or lessee; and any person who is in control of that nuisance is guilty of maintaining a nuisance and shall be enjoined as provided in sections 3767.03 to 3767.11 of the Revised Code."

458. Defendants are persons who have established or conducted a nuisance, who have aided or abetted in the establishment or conduct of a nuisance, and/or who are in control of a nuisance and guilty of maintaining a nuisance; as defined in R.C. § 3767.02.

459. Defendants are persons who have violated, and/or who have aided and abetted the violation of the laws of Ohio or of the United States of America or of any rule of the board of pharmacy controlling the distribution of a drug of abuse as defined in R.C. § 3719.011.

460. In the distribution, dispensing, and sale of opioids in Fayette County, Defendants violated and/or aided and abetted the violation of Ohio law, including, but not limited to, R.C. § 4729.01(F), R.C. §§ 4729.51-4729.53, and O.A.C. §§ 4729-9-12, 4729-9-16, 4729-9-28, 4729-9-05(A), 4729-9-11, 4729-5-20(G), 4729-5-21(A), 4729-5-30(A), and federal law, including, but not limited to, 21 U.S.C.A. § 823 and 21 C.F.R. § 1301.74.

461. Defendants' unlawful conduct includes violating and/or aiding and abetting the violation of federal and Ohio statutes and regulations, including the controlled substances laws, by, *inter alia*:

a. Distributing, dispensing, and/or selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing, dispensing, and/or selling opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to stop or suspend shipments of suspicious orders; and

d. Distributing, dispensing, and/or selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

462. In the distribution and sale of opioids in Ohio and Fayette County, Defendants violated and/or aided and abetted violations of R.C. § 2925.02(A), which states: "No person shall knowingly do any of the following:

(1) By force, threat, or deception, administer to another or induce or cause another to use a controlled substance; . . . or

(3) By any means, administer or furnish to another or induce or cause another to use a controlled substance, and thereby cause serious physical harm to the other person, or cause the other person to become drug dependent."

463. The exemption in R.C. § 2925.02 only applies to drug manufacturers, distributors, and pharmacies when their "conduct is in accordance with Chapters R.C. 3719., 4715., 4723., 4729., 4730., 4731., and 4741." R.C. § 2925.02(B). Defendants are not in compliance with said Chapters and have thereby forfeited the protection provided by the exception.

464. Defendants' conduct entails a pervasive pattern and practice of violating the statutes and regulations set forth above. Defendants' systemic failure to adhere to Ohio and federal controlled substances statutes and regulations has created an ongoing, significant, unlawful, and

unreasonable interference with the public health, welfare, safety, peace, comfort, and convenience in Fayette County.

465. Defendants had control over their conduct in Fayette County and that conduct has had an adverse effect on the public right. Marketing Defendants controlled their deceptive advertising and efforts to mislead the public, including their acts and omissions in detailing by their sales representatives, online communications, publications, Continuing Medical Education programs and other speaking events, and other means described in this Complaint. All Defendants had control over their own shipments of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. The Chain Pharmacies controlled their dispensing of opioids. Each of the Defendants controlled the systems it developed to prevent diversion, and whether it filled orders it knew or should have known were likely to be diverted or fuel an illegal market.

466. The nuisance created by Defendants' conduct is abatable.

467. Defendants' misconduct alleged in this case is ongoing and persistent.

468. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The County alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

469. The County has incurred expenditures for special programs over and above its ordinary public services.

470. The unlawful conduct of each Defendant was a substantial factor in producing harm to the County

471. The County seeks abatement, recovery of abatement costs, injunctive relief, and to prevent injury and annoyance from any nuisance.

472. The County seeks all other equitable relief as allowed by law.

COUNT II
Common Law Absolute Public Nuisance
(Against All Defendants)
(Brought by the County of Fayette, the Plaintiff in this Count)

473. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein unless inconsistent with the allegations in this Count, and further alleges:

474. Defendants created and maintained a public nuisance which proximately caused injury to the County.

475. A public nuisance is an unreasonable interference with a right common to the general public.

476. Defendants have created and maintained a public nuisance by marketing, distributing, and selling opioids in ways that unreasonably interfere with the public health, welfare, and safety in Fayette County, and the County and its residents have a common right to be free from such conduct and to be free from conduct that creates a disturbance and reasonable apprehension of danger to person and property.

477. The public nuisance is an *absolute* public nuisance because Defendants' nuisance-creating conduct was intentional and unreasonable and/or violated statutes which established specific legal requirements for the protection of others.

478. Defendants have created and maintained an absolute public nuisance through their ongoing conduct of marketing, distributing, and selling opioids, which are dangerously addictive drugs, in a manner which caused prescriptions and upon information and belief, use of opioids to skyrocket in Fayette County, flooded Fayette County with opioids, and facilitated and encouraged

the flow and diversion of opioids into an illegal, secondary market, resulting in devastating consequences to the County and its residents.

479. Defendants know, and have known, that their intentional, unreasonable, and unlawful conduct will cause, and has caused, opioids to be used and possessed illegally and that their conduct has produced an ongoing nuisance that has had, and will continue to have, a detrimental effect upon the public health, welfare, safety, peace, comfort, and convenience of Fayette County and its residents.

480. Defendants' conduct has created an ongoing, significant, unlawful, and unreasonable interference with rights common to the general public, including the public health, welfare, safety, peace, comfort, and convenience of Fayette County and its residents. *See* Restatement (Second) of Torts § 821B.

481. The interference is unreasonable because Defendants' nuisance-creating conduct:

a. Involves a significant interference with the public health, the public safety, the public peace, the public comfort, and/or the public convenience;

b. At all relevant times was and is proscribed by state and federal laws and regulations; and/or

c. Is of a continuing nature and, as Defendants know, has had and is continuing to have a significant effect upon rights common to the general public, including the public health, the public safety, the public peace, the public comfort, and/or the public convenience.

482. The significant interference with rights common to the general public is described in detail throughout this Complaint and includes:

a. The creation and fostering of an illegal, secondary market for prescription opioids;

b. Easy access to prescription opioids by children and teenagers;

c. A staggering increase in opioid abuse, addiction, overdose, injuries, and deaths;

d. Infants being born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts;

e. Employers have lost the value of productive and healthy employees; and

f. Increased costs and expenses for the County relating to healthcare services, law enforcement, the criminal justice system, social services, and education systems.

483. Defendants intentionally and unreasonably and/or unlawfully marketed and pushed as many opioids onto the market as possible, fueling addiction to and diversion of these powerful narcotics, resulting in increased addiction and abuse, an elevated level of crime, death and injuries to the residents of Fayette County, a higher level of fear, discomfort and inconvenience to the residents of Fayette County, and direct costs to the County.

484. Each Defendant is liable for creating the public nuisance because the intentional and unreasonable and/or unlawful conduct of each Defendant was a substantial factor in producing the public nuisance and harm to the County.

485. A violation of any rule or law controlling the sale and/or distribution of a drug of abuse in Fayette County constitutes an absolute public nuisance. *See e.g.* R.C. § 4729.35 ("The violation by a . . . person of any laws of Ohio or of the United States of America or of any rule of the board of pharmacy controlling the distribution of a drug of abuse . . . constitute[s] a public nuisance[.]").

486. In the sale and distribution of opioids in Ohio and Fayette County, Defendants violated federal law, including, but not limited to, 21 U.S.C.A. § 823 and 21 C.F.R. § 1301.74, and Ohio law, including, but not limited to, R.C. § 4729.01(F), R.C. §§ 4729.51-4729.53, and O.A.C. §§ 4729-912, 4729-9-16, 4729-9-28, 4729-9-05(A), 4729-9-11, 4729-5-20(G), 4729-5-21(A), and 4729-5-30(A).

487. Defendants' unlawful nuisance-creating conduct includes violating federal and Ohio statutes and regulations, including the controlled substances laws, by:

a. Distributing, dispensing, and/or selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing, dispensing, and/or selling opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to effectively monitor for suspicious orders;

d. Choosing not to investigate suspicious orders;

e. Choosing not to report suspicious orders;

f. Choosing not to stop or suspend shipments of suspicious orders; and

g. Distributing, dispensing, and/or selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

488. Defendants' intentional and unreasonable nuisance-creating conduct, for which the gravity of the harm outweighs the utility of the conduct, includes:

a. Distributing, dispensing, and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing, dispensing, and/or selling opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to effectively monitor for suspicious orders;

d. Choosing not to investigate suspicious orders;

e. Choosing not to report suspicious orders;

f. Choosing not to stop or suspend shipments of suspicious orders; and

g. Distributing, dispensing, and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

489. Defendants intentionally and unreasonably distributed, dispensed, and sold opioids that Defendants knew would be diverted into the illegal, secondary market and would be obtained by persons with criminal purposes.

490. As evidence of addiction and abuse of opioids widened, Defendants were obligated to rein in their supply, prevent diversion, and mitigate the harms from opioid overuse and abuse, but intentionally and unreasonably failed to do so.

491. Marketing Defendants intentionally and unreasonably engaged in a deceptive marketing scheme that was designed to, and successfully did, change the perception of opioids and cause their prescribing and sales to skyrocket in Fayette County.

492. Marketing Defendants intentionally and unreasonably misled the County, healthcare providers, and the public about the risks and benefits of opioids, including minimizing the risks of addiction and overdose and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain.

493. Marketing Defendants violated Ohio and federal statutes and regulations, including the controlled substances laws, by engaging in the deceptive marketing of opioids, as described in this Complaint.

494. In the distribution and sale of opioids in Ohio and Fayette County, Defendants violated and/or aided and abetted violations of R.C. § 2925.02(A), which states: "No person shall knowingly do any of the following:

> (1) By force, threat, or deception, administer to another or induce or cause another to use a controlled substance; . . . or
>
> (3) By any means, administer or furnish to another or induce or cause another to use a controlled substance, and thereby cause serious physical harm to the other person, or cause the other person to become drug dependent."

495. Defendants are in the business of manufacturing, marketing, selling, dispensing and/or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because *inter alia* these drugs are defined under federal and state law as substances posing a high potential for abuse and addiction.

496. Indeed, opioids are akin to medical grade heroin. Defendants' wrongful conduct of deceptively marketing and pushing as many opioids onto the market as possible led directly to the public nuisance and harm to the County—exactly as would be expected when medical-grade heroin in the form of prescription opioids are deceptively marketed, flood the community, and are diverted into an illegal, secondary market.

497. Defendants had control over their conduct in Fayette County and that conduct has had an adverse effect on rights common to the general public. Marketing Defendants controlled their deceptive advertising and efforts to mislead the public, including their acts and omissions in detailing by their sales representatives, online communications, publications, Continuing Medical Education programs and other speaking events, and other means described in this Complaint. All Defendants had control over their own shipments of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. The Chain Pharmacies controlled their dispensing of opioids. Each of the Defendants controlled the systems it developed to prevent diversion, and whether it filled orders it knew or should have known were likely to be diverted or fuel an illegal market.

498. It was reasonably foreseeable that Defendants' actions and omissions would result in the public nuisance and harm to the County described herein.

499. Because of Marketing Defendants' deceptive marketing of opioids and because of Defendants' special positions within the closed system of opioid distribution, without Defendants'

actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

500. The public nuisance created by Defendants' actions is substantial and unreasonable. It has caused and continues to cause significant harm to Fayette County and the harm inflicted outweighs any offsetting benefit.

501. The externalized risks associated with Defendants' nuisance-creating conduct as described herein greatly exceed the internalized benefits.

502. As a direct and proximate result of Defendants' wrongful conduct and the public nuisance created by Defendants, the County has taken proactive measures to abate the public nuisance, and the County seeks to expand these efforts.

503. The nuisance created by Defendants' conduct is abatable.

504. Defendants' misconduct alleged in this case is ongoing and persistent.

505. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The County alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

506. The County has incurred expenditures for special programs over and above its ordinary public services.

507. The County seeks to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions and unreasonable interference with rights common to the general public.

508. The tortious conduct of each Defendant was a substantial factor in creating the absolute public nuisance.

509. The tortious conduct of each Defendant was a substantial factor in producing harm to the County.

510. The County has suffered an indivisible injury as a result of the tortious conduct of Defendants.

511. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

512. The County asserts this Cause of Action as a common law tort claim for absolute public nuisance and not as a "product liability claim" as defined in R.C. § 2307.71. In this Count, the County does not seek damages for death, physical injury to person, emotional distress, or physical damage to property, as defined under the Ohio Product Liability Act.

513. The County seeks all equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, attorney fees and costs, and pre- and post-judgment interest.

COUNT III
Common Law Qualified Public Nuisance
(Against All Defendants)
(Brought by the County of Fayette, the Plaintiff in this Count)

514. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein unless inconsistent with the allegations in this Count, and further alleges:

515. The excessive and unreasonable oversupply of Opioids in Fayette County constitutes a public nuisance in that it unreasonably interfered with rights common to the general

public, including the public health, welfare, safety, peace, comfort, and convenience of Fayette County and its residents. *See* Restatement (Second) of Torts § 821B.

516. The significant interference with rights common to the general public is described in detail throughout this Complaint and includes:

a. A staggering increase in opioid abuse, addiction, overdose, injuries, and deaths throughout the County, including infants who are born addicted to opioids due to prenatal exposure;

b. A corresponding increase in abuse, addiction, overdose, injuries and deaths related to the transition from opioid pills to heroin, fentanyl, and carfentanyl;

c. The necessity for governmental intervention from Federal, State and Local governments to provide services for, among other things, healthcare, law enforcement, criminal justice, social services, and education related to the Opioid epidemic;

517. Defendants' conduct in marketing, distributing, dispensing, and selling opioids created or contributed to the creation or maintenance of this public nuisance. Defendants' conduct caused prescriptions and sales of opioids to skyrocket in Fayette County and flooded the County with opioids, and facilitated and encouraged the flow and diversion of opioids into an illegal, secondary market, resulting in devastating consequences to the County and its residents.

518. Marketing Defendants created or contributed to the creation and/or maintenance of the public nuisance by:

a. negligently, unreasonably and/or unlawfully engaging in a deceptive marketing scheme that was designed to, and successfully did, change the perception of opioids and upon information and belief, cause their prescribing and sales to skyrocket in the County.

b. negligently, unreasonably and/or unlawfully misleading the County, healthcare providers, and the public about the risks and benefits of opioids, including minimizing the risks of addiction and overdose and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain.

c. violating Ohio and federal statutes and regulations, including the controlled substances laws, by engaging in the deceptive marketing of opioids, as described in this Complaint.

d. negligently, unreasonably and/or unlawfully deceptively marketing opioids, including minimizing the risks of addiction and overdose and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain.

519. All Defendants' created or contributed to the creation and/or maintenance of the public nuisance by:

a. negligently, unreasonably and/or unlawfully distributing, dispensing, and/or selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. negligently, unreasonably and/or unlawfully distributing, dispensing, and/or selling opioids without maintaining effective controls against the diversion of opioids;

c. negligently, unreasonably and/or unlawfully failing to effectively monitor for suspicious orders;

d. negligently, unreasonably and/or unlawfully failing to investigate suspicious orders;

e. negligently, unreasonably and/or unlawfully failing to report suspicious orders;

f. negligently, unreasonably and/or unlawfully failing to stop or suspend shipments of suspicious orders; and

g. negligently, unreasonably and/or unlawfully distributing, dispensing, and/or selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

520. Defendants know, and should have known, that their unreasonable, and unlawful conduct does cause, has caused, and will continue to cause, excessive availability of opioids in Fayette County and that their conduct has produced an ongoing nuisance that has had, and will continue to have, a detrimental effect upon the public health, welfare, safety, peace, comfort, and convenience of Fayette County and its residents.

521. Despite this knowledge, Defendants negligently, unreasonably and/or unlawfully marketed and pushed as many opioids onto the market as possible, fueling addiction to and diversion of these powerful narcotics.

522. Defendants owed the County legal duties, including:

a. a preexisting duty, to not expose the County and its residents to an unreasonable risk of harm. Defendants' conduct, as detailed herein, breached that duty

b. a duty to exercise reasonable and ordinary care and skill in accordance with applicable standards of conduct in manufacturing, advertising, marketing, selling, dispensing, and/or distributing opioids

c. a duty not to breach the standard of care established under Ohio law and the federal Controlled Substances Act ("CSA") and their respective implementing regulations to report suspicious prescribing and to maintain systems to detect and report such activity.

523. As evidence of addiction and abuse of opioids widened, Defendants were obligated to rein in their supply, prevent diversion, and mitigate the harms from opioid overuse and abuse, but intentionally and unreasonably failed to do so.

524. The degree of care the law requires is commensurate with the risk of harm the conduct creates. Defendants' conduct in marketing, distributing, dispensing, and selling dangerously addictive drugs requires a high degree of care and places them in a position of great trust and responsibility *vis a vis* the County. Their duty cannot be delegated.

525. Each Defendant breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in selling dangerous controlled substances.

526. The County does not only allege that Defendants were negligent for failure to protect from harm. Defendants engaged in affirmative conduct, the foreseeable result of which was to cause harm to the County.

527. It was reasonably foreseeable that Defendants' actions and omissions would result in the public nuisance and harm to the County described herein. Reasonably prudent manufacturers, distributors, and dispensers of prescription opioids would have anticipated that the conduct alleged herein would create a public nuisance in the County, and that the public nuisance created would unreasonably interfere with the public health, safety, comfort and convenience of the County and its residents.

528. Defendants had control over their conduct in the County and that conduct has created a public nuisance, unreasonably interfering with rights common to the general public. Marketing Defendants controlled their deceptive advertising and efforts to mislead the public and physicians, including their acts and omissions in detailing by their sales representatives, online communications, publications, Continuing Medical Education programs and other speaking events, and other means described in this Complaint. Defendants had control over their own shipments of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. Each of the Defendants controlled the systems it developed to prevent diversion, including whether it filled orders it knew or should have known were likely to be diverted or fuel an illegal market.

529. The public nuisance created by Defendants' actions is substantial and unreasonable. It has caused and continues to cause significant harm to Fayette County and the harm inflicted outweighs any offsetting benefit.

530. As a direct and proximate result of Defendants' tortious conduct and the public nuisance created by Defendants, the County has taken proactive measures to abate the public nuisance, and the County seeks to expand these efforts.

531. The nuisance created by Defendants' conduct is abatable.

532. Defendants' misconduct alleged in this case is ongoing and persistent.

533. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The County alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

534. The County has incurred expenditures for special programs over and above its ordinary public services.

535. The County seeks to abate the nuisance created by the Defendants' unreasonable, unlawful, negligent, ongoing, continuing, and persistent actions and omissions and unreasonable interference with rights common to the general public.

536. The County's claims are not based upon or derivative of the rights of others.

537. The tortious conduct of each Defendant was a substantial factor in creating the qualified public nuisance.

538. The qualified public nuisance was a substantial factor in producing harm to the County.

539. The County has suffered an indivisible injury as a result of the tortious conduct of Defendants.

540. Each Defendant is joint and severally liable for creating the public nuisance.

541. The County asserts this Cause of Action as a common law tort claim for qualified public nuisance and not as a "product liability claim" as defined in R.C. § 2307.71. In this Count, the County does not seek damages for death, physical injury to person, emotional distress, or physical damage to property, as defined under the Ohio Product Liability Act.

542. The County seeks all equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, attorney fees and costs, and pre- and post-judgment.

COUNT IV
Ohio Corrupt Practices Act ("OCPA")
R.C. 2923.31 *et seq.*
(Against Defendants Purdue, Teva, Janssen, Endo, and Mallinckrodt
(the "Opioid Marketing Enterprise"))
(Brought by the County of Fayette, the Plaintiff in this Count)

543. The County incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

544. Defendants Purdue, Teva, Janssen, Endo, and Mallinckrodt ("Defendants," for purposes of this Count) are "persons" within the meaning of R.C. § 2923.31(G) who conducted the affairs of an enterprise through a pattern of corrupt activity, hereinafter the "Opioid Marketing Enterprise," in violation of R.C. § 2923.31.

545. The County is a "person," as that term is defined in R.C. § 2923.31, who was injured as a result of Defendants' wrongful conduct.

546. Under R.C. § 2923.32:

> (A)(1) No person employed by, or associated with, any enterprise shall conduct or participate in, directly or indirectly, the affairs of the enterprise through a pattern of corrupt activity or the collection of an unlawful debt.
>
> (2) No person, through a pattern of corrupt activity or the collection of an unlawful debt, shall acquire or maintain, directly or indirectly, any interest in, or control of, any enterprise or real property.
>
> (3) No person, who knowingly has received any proceeds derived, directly or indirectly, from a pattern of corrupt activity or the collection of any unlawful debt, shall use or invest, directly or indirectly, any part of those proceeds, or any proceeds derived from the use or investment of any of those proceeds, in the acquisition of any title to, or any right, interest, or equity in, real property or in the establishment or operation of any enterprise.

A. Description of the Enterprise

547. Defendants were members of a legal entity enterprise within the meaning of R.C. § 2923.31(C). Defendants formed an association-in-fact enterprise – sometimes referred to in this Complaint as the "Opioid Marketing Enterprise." The Opioid Marketing Enterprise consists of Defendants, including their employees and agents, and the front groups and KOLs described above.

548. Alternatively, each of the above-named Defendants constitutes a single legal entity or associated-in-fact "enterprise" within the meaning of R.C. § 2923.31(C), through which the members of the enterprise conducted a pattern of corrupt activity. The Opioid Marketing Enterprise is an ongoing and continuing business organization that created and maintained systematic links for a common purpose: to ensure the prescription of opioids for chronic pain.

549. Defendants formed the Opioid Marketing Enterprise for the purpose of unlawfully increasing demand for, and thus sales of and revenues and profits from prescription opioids by maintaining an oversupply of prescription opioids through illegal practices, including committing fraud and drug offenses (as laid out above and below). Defendants, through the Opioid Marketing Enterprise, concealed the true risks and dangers of opioids from the medical community and the public, including the County, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. This fraudulent scheme was intended to, and did, change prescriber habits and public perception about the risks and benefits of opioid use.

550. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each Defendant; and (b) was separate and distinct from the pattern of corrupt activity in which Defendants engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of the Defendants; (d) was characterized

by interpersonal relationships between and among each member of the Opioid Marketing Enterprise, including between the Defendants and each of the Front Groups and KOLs; (e) had sufficient longevity for the enterprise to pursue its purpose and functioned as a continuing unit.

551. Upon information and belief, each of the Defendants in the Opioid Marketing Enterprise had a systematic link to each other through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by these Defendants. They coordinated for example, by funding the same front groups and unbranded publications. Their coordination can also be inferred through the consistent misrepresentations described in this Complaint. Further, the Defendants coordinated through groups such as the PCF; this coordination in lobbying is additional evidence that they engaged in other concerted efforts as well.

552. Through their personal relationships, the members of the Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the Opioid Marketing Enterprise's common purpose.

553. Upon information and belief, Defendants exerted substantial control over the Opioid Marketing Enterprise through communications with each other, with the front groups, and with KOLs described in this Complaint.

554. There was, upon information and belief, regular communication between Defendants, Front Groups and KOLs, in which information was shared, misrepresentations are coordinated, and payments were exchanged. Typically, the coordination, communication and payment occurred, and continues to occur, through the repeated and continuing use of the wires and mail in which Defendants, Front Groups, and KOLs share information regarding overcoming objections and resistance to the use of opioids for chronic pain. The Defendants, Front Groups and KOLs functioned as a continuing unit for the purpose of implementing the Opioid Marketing

Enterprise's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.

555. But for the Opioid Marketing Enterprise's unlawful fraud, the Front Groups would have had incentives to disclose the deceit by the Defendants and the Opioid Marketing Enterprise to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

B. Conduct of the Enterprise

556. During the time period alleged in this Complaint, Defendants exerted control over, conducted and/or participated in the Opioid Marketing Enterprise by fraudulently marketing opioids for the treatment of chronic pain. In devising and executing the illegal scheme, the members of the Opioid Marketing Enterprise devised and knowingly carried out a material scheme and/or artifice to defraud the County and the public to obtain money by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the risks, benefits, and superiority of opioids in general and their opioids in particular.

C. Pattern of Corrupt Activity

557. Defendants conducted and participated in the conduct of the affairs of the Opioid Marketing Enterprise, through a pattern of corrupt activity as defined in R.C. § 2923.31(E) & (I)(2).

558. Corrupt activities as defined in R.C. § 2923.31(I) include, among other things: engaging in, attempting to engage in, conspiring to engage in, or soliciting, coercing, or intimidating another person to engage in any conduct defined as racketeering activity under the Organized Crime Control Act of 1970, 84 Stat. 941, 18 U.S.C. 1961(1)(B), (1)(C), (1)(D), and (1)(E), as amended; and, any "violation of section . . 2913.05."

559. A "'pattern of corrupt activity' means two or more incidents of corrupt activity, whether or not there has been a prior conviction, that are related to the affairs of the same enterprise, are not isolated, and are not so closely related to each other and connected in time and place that they constitute a single event." R.C. § 2923.31(E).

560. Incidents of corrupt activity include, but are not limited to:

Mail Fraud. The members of Opioid Marketing Enterprise violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, fraudulent materials via U.S. mail or commercial interstate carriers for the purpose of selling opioids for chronic pain.

Wire Fraud: The members of Opioid Marketing Enterprise violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, fraudulent materials by wire for the purpose of selling opioids for chronic pain.

Telecommunications Fraud: The members of Opioid Marketing Enterprise violated R.C. 2913.05 by "knowingly disseminat[ing], transmit[ing], or caus[ing] to be disseminated or transmitted by means of a wire, radio, satellite, telecommunication, telecommunications device, or telecommunications service any writing, data, sign, signal, picture, sound, or image with purpose to execute or otherwise further the scheme to defraud."

Violation of Controlled Substances Act. The members of the Opioid Marketing Enterprise violated 21 U.S.C. § 483(a)(4), which makes it unlawful "for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information form, any application, report, record or other document required to be made, kept or filed under this subchapter," and a violation of which is punishable by up to four years in jail, *see* 21 U.S.C. § 483(d)(1), making it a felony.

561. Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in furtherance of these Defendants' fraudulent scheme and common course of conduct to expand the market for their opioids and increase their profits through misleading and deceptive marketing. This conduct in furtherance of the Opioids Marketing Enterprise likely involved thousands of separate communications.

562. The multiple acts of corrupt activity which the members of the Opioid Marketing Enterprise committed, or aided or abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of corrupt activity."

563. Defendants' control and participation in the Opioid Marketing Enterprise were necessary for the successful activity in which these Defendants engaged that included, but was not limited to the acts detailed above and the following acts:

a. Defendants created a body of deceptive and unsupported medical and popular literature about opioids that: (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was thus more likely to be relied upon by physicians and patients;

b. Defendants selected, cultivated, promoted, and paid the KOLs based on their willingness to communicate and distribute these Defendants' messages about the use of opioids for chronic pain;

c. Defendants provided substantial opportunities for KOLs to participate in research studies on topics these Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

d. Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs supportive of the use of opioids for chronic pain;

e. Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be publications put out by independent Front Groups;

f. Defendants sponsored CME programs put on by front groups that focused exclusively on the use of opioids for chronic pain; and

g. Defendants developed and disseminated pro-opioid treatment guidelines.

564. The Opioid Marketing Enterprise had a hierarchical decision-making structure that was headed by Defendants and corroborated by the KOLs and Front Groups. The Defendants controlled representations made about their opioids and their drugs, doled out payments to KOLs, and ensured that representations made by KOLs, Front Groups, and Defendants' sales detailers were consistent with the Defendants' messaging throughout the United States and Ohio. The Front Groups and KOLS in the Opioid Marketing Enterprise were dependent on the Defendants for their financial structure and for career development and promotion opportunities.

565. Defendants concealed their relationship to and control of front groups and KOLs, who appeared to be independent but were not, from the County and the public at large; and Defendants intended that front groups and KOLs would distribute promotional and other materials that misrepresented the risks, benefits, and superiority of opioids.

566. Defendants worked together with each other through the Front Groups that they jointly funded and through which they collaborated on the joint promotional materials described above.

567. The Front Groups also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The Front Groups promised to, and did, make representations regarding Defendants' opioids, and opioids generally that were consistent with Defendants' messages;

b. The Front Groups distributed promotional and other materials which deceptively claimed that opioids could be safely used for chronic pain and that the benefits of using opioids for chronic pain outweighed the risks; and

c. The Front Groups concealed their connections to Defendants.

568. Meanwhile, these front groups, "with their large numbers and credibility with policymakers and the public—have 'extensive influence in specific disease areas.'"[159] The larger front groups "likely have a substantial effect on policies relevant to their industry sponsors."[160] "By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic."[161]

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[159] *Fueling an Epidemic,*" *supra* n. 224, p. 2.

[160] *Id.* p. 1.

[161] *Id.* at 2.

569. The KOLs also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

a. The KOLs promised to, and did, make representations regarding Defendants' opioids that were consistent with Defendants' messages themselves;

b. The KOLs distributed promotional and other materials which deceptively claimed that opioids could be safely used for chronic pain and that the benefits of using opioids for chronic pain outweighed the risks; and

c. The KOLs concealed their connections to and sponsorship by Defendants.

570. The scheme devised and implemented by Defendants and members of the Opioid Marketing Enterprise, amounted to a common course of conduct intended to increase the Defendants' sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

571. As detailed above, Defendants committed various fraudulent acts which constitute fraud and a scheme to defraud. These intentional omissions of material fact and affirmative representations made by Defendants were false when made which included but was not limited to the acts detailed above and the following acts:

a. Marketing materials about the Defendants' opioids, and their risks and benefits, which Defendants distributed and made available to health care providers and consumers located across the country and in Fayette County;

b. Unbranded marketing materials about the use of opioids in treating chronic pain, and their risks and benefits, which Defendants distributed and made available to health care providers and consumers located across the country, including in Fayette County;

c. Websites and on-line CMEs about the use of opioids in treating chronic pain, and their risks and benefits, which the Defendants, directly and through their Front Groups, made available to health care providers and consumers located across the country and in Fayette County;

d. Upon information and belief, written representations and telephone calls between Defendants and front groups regarding representations about Defendants' opioids, or the use of opioids for chronic pain generally;

e. Upon information and belief, distributing materials and talking points to sales representatives electronically and by mail and phone;

f. Upon information and belief, written representations and telephone calls between Defendants and KOLs regarding Defendants' opioids, or the use of opioids for chronic pain generally;

g. Upon information and belief, e-mails between the Defendants and the Front Groups agreeing to or effectuating the implementation of the opioid marketing scheme;

h. Upon information and belief, e-mails between the Defendants and KOLs agreeing to or effectuating the implementation of the opioid marketing scheme; and

i. Receipts of increased profits which represented the wrongful proceeds of the scheme.

572. As described above, the County's allegations in this Count are based on violations of each of the legal duties, statutes, and regulations described in this Complaint, including the violations of Ohio laws and regulations.

573. The multiple acts of corrupt activity which the members of the Opioid Marketing Enterprise committed, or aided or abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of corrupt activity," through which the Defendants, the Front Groups and the KOLs defrauded and intended to defraud Ohio consumers, the County, and other intended victims.

574. The pattern of corrupt activity used by Defendants and the Opioid Marketing Enterprise likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioid Marketing Enterprise, including essentially uniform misrepresentations, concealments and material omissions regarding the beneficial uses

and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain, with the goal of profiting from increased sales of the Defendants' drugs.

D. Damages

575. Defendants' substantial financial contribution to the Opioid Marketing Enterprise, and the advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.[162]

576. The Defendants' violations of law and their pattern of corrupt activity directly or indirectly caused the County's injury. The Defendants' pattern of corrupt activity logically, substantially and foreseeably caused an opioid epidemic. The County's injuries, as described below, were not unexpected, unforeseen or independent. Rather, as the County alleges, the Defendants knew that the opioids were unsuited to treatment of long-term chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse. Nevertheless, the Defendants engaged in a scheme of deception, that utilized the mail and wires as part of their fraud, in order to increase sales of their opioid products.

577. It was foreseeable and expected that a massive marketing campaign utilized by the Defendants that misrepresented the risks and benefits of prescription opioids would lead to a nationwide opioid epidemic, and a devastating public health crisis in Fayette County. The County's injuries were logically, foreseeable, and substantially caused by the opioid epidemic that Defendants created.

578. Defendants' pattern of corrupt activity directly and proximately caused the County injury because it paid for costs associated with the opioid epidemic, as described above in language expressly incorporated herein by reference. But for Defendants' conduct, the County would not

[162] *Fueling an Epidemic*, *supra* note 224, p. 1.

have incurred the costs for health care and addiction treatment, law enforcement, child welfare, and other expenditures required as a result of the opioid epidemic.

579. The County's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

a. Losses caused by the decrease in funding available for the County's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

b. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

c. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;

d. Costs associated with providing police officers, firefighters, and emergency and/or first responders with Naloxone – an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

e. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;

f. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;

g. Costs for providing treatment of infants born with opioid-related medical conditions, or born addicted to opioids due to drug use by mother during pregnancy;

h. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased drug-addicted population;

i. Costs associated with increased burden on the County's judicial system, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;

e. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;

f. Loss of tax revenue due to the decreased efficiency and size of the working population in the County;

g. Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and

h. Losses caused by diminished property values in the form of decreased business investment and tax revenue.

580. The misconduct alleged in this case is ongoing and persistent.

581. The misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The County alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

582. The County has incurred expenditures for special programs over and above its ordinary public services.

583. The County seeks all legal and equitable relief as allowed by law, including, *inter alia,* actual damages; treble damages; equitable and/or injunctive relief, including corrective statements, information and education, under R.C. § 2923.34(B)(1)-(2), requiring divestiture by, and reasonable restrictions upon, the future activities of the Defendants; forfeiture as deemed proper by the Court; attorney's fees and all costs; expenses of suit; and pre- and post-judgment interest, as the Court deems just and applicable.

Count V
Violation of the Ohio Corrupt Practices Act
Ohio Revised Code § 2923.31, *et seq.*
Against Defendants Purdue, Teva, Endo. Mallinckrodt, McKesson, Cardinal, and AmerisourceBergen (The "Opioid Supply Chain Enterprise")
(Brought by The County of Fayette, the Plaintiff in this Count)

584. The County incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges as follows.

585. The County brings this Claim against Defendants Purdue, Teva, Endo, Mallinckrodt, McKesson, Cardinal, and AmerisourceBergen (the "Supply Chain Defendants"), each of whom is a "person" within the meaning of R.C. § 2923.31(G).

A. The Opioid Supply Chain Enterprise and Pattern of Corrupt Activity

586. The Defendants are "persons" within the meaning of R.C. § 2923.31(G) who conducted the affairs of an enterprise through a pattern of corrupt activity, in violation of R.C. § 2923.31.

587. The County is a "person," as that term is defined in R.C. § 2923.31, who was injured in its business or property as a result of Defendants' wrongful conduct.

588. Under R.C. § 2923.32:

> (A)(1) No person employed by, or associated with, any enterprise shall conduct or participate in, directly or indirectly, the affairs of the enterprise through a pattern of corrupt activity or the collection of an unlawful debt.
>
> (2) No person, through a pattern of corrupt activity or the collection of an unlawful debt, shall acquire or maintain, directly or indirectly, any interest in, or control of, any enterprise or real property.
>
> (3) No person, who knowingly has received any proceeds derived, directly or indirectly, from a pattern of corrupt activity or the collection of any unlawful debt, shall use or invest, directly or indirectly, any part of those proceeds, or any proceeds derived from the use or investment of any of those proceeds, in the acquisition of any title to, or any right, interest, or equity in, real property or in the establishment or operation of any enterprise.

589. Defendants conducted the affairs of an enterprise through a pattern of corrupt activity, hereinafter the "Opioid Supply Chain Enterprise," in violation of R.C. § 2923.32.

590. Defendants together were members of a legal entity enterprise within the meaning of R.C. § 2923.31(C). These Defendants formed an association-in-fact enterprise – sometimes

referred to in this Complaint as the "Opioid Supply Chain Enterprise." The Opioid Supply Chain Enterprise consists of these Defendants, including their employees and agents. Along with the Defendants, trade organizations, including the HDA and PCF participated in the enterprise.

591. Alternatively, each of the above-named Defendants constitutes a single legal entity or associated-in-fact "enterprise" within the meaning of R.C. § 2923.31(C), through which the members of the enterprise conducted a pattern of corrupt activity. The Supply Chain Defendants together formed an association-in-fact enterprise, the Opioid Supply Chain Enterprise, for the purpose of profiting from the increased volume of opioid sales in the United States. The Opioid Supply Chain Enterprise is an association-in-fact enterprise within the meaning of § 1961. The Opioid Supply Chain Enterprise consists of the Supply Chain Defendants.

592. The Supply Chain Defendants were members the Healthcare Distribution Alliance (the "HDA"). Each of the Supply Chain Defendants is a member, participant, and/or sponsor of the HDA, and utilized the HDA to form the interpersonal relationships of the Opioid Supply Chain Enterprise and to assist them in engaging in the pattern of corrupt activity that gives rise to the Count.

593. At all relevant times, the Opioid Supply Chain Enterprise: (a) had an existence separate and distinct from each of the Supply Chain Defendants; (b) was separate and distinct from the pattern of corrupt activity in which the Supply Chain Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the Supply Chain Defendants; (d) was characterized by interpersonal relationships among the Supply Chain Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. Each of the Supply Chain Defendants conducted and participated in the

conduct of the affairs of this Enterprise through a pattern of "corrupt activities" as defined in Ohio Rev. Code Ann.§ 2923.31(I)(1) and (2).

594. Corrupt activities as defined in R.C. § 2923.31(I) include, among other things: engaging in, attempting to engage in, conspiring to engage in, or soliciting, coercing, or intimidating another person to engage in any conduct defined as racketeering activity under the Organized Crime Control Act of 1970, 84 Stat. 941, 18 U.S.C. § 1961(1)(B), (1)(C), (1)(D), and (1)(E), as amended; and, any "violation of [R.C.] section . . 2913.05."

595. A "'pattern of corrupt activity' means two or more incidents of corrupt activity, whether or not there has been a prior conviction, that are related to the affairs of the same enterprise, are not isolated, and are not so closely related to each other and connected in time and place that they constitute a single event." R.C. § 2923.31(E).

596. The Supply Chain Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of corrupt activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343 and R.C. § 2913.05) within the past ten years. The multiple acts of corrupt activity that the Supply Chain Defendants committed, or aided and abetted in the commission of, were related to each other, and posed a threat of continued corrupt activity. The corrupt activity was made possible by the Supply Chain Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Supply Chain Enterprise. The Supply Chain Defendants participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in intrastate and/or interstate or foreign commerce.

597. The Supply Chain Defendants also conducted and participated in the conduct of the affairs of the Opioid Supply Chain Enterprise through a pattern of corrupt activity by the felonious importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance

or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States. The Supply Chain Defendants committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

598. Each of the Supply Chain Defendants is a registrant as defined in the CSA and must be registered or licensed under Ohio law. Ohio law and their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances, and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

599. The Supply Chain Defendants' incidents of corrupt activity include, but are not limited to:

Mail Fraud. The members of the Opioid Supply Chain Enterprise violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, fraudulent materials via U.S. mail or commercial interstate carriers for the purpose of increasing sales and profits.

Wire Fraud: The members of the Opioid Supply Chain Enterprise violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, fraudulent materials by wire for the purpose of increasing sales and profits.

Telecommunications Fraud: The members of the Opioid Supply Chain Enterprise violated R.C. § 2913.05 by "knowingly disseminat[ing], transmit[ing], or caus[ing] to be disseminated or transmitted by means of a wire, radio, satellite, telecommunication, telecommunications device, or telecommunications service any writing, data, sign, signal, picture, sound, or image with purpose to execute or otherwise further the scheme to defraud."

Violation of Controlled Substances Act. The members of the Opioid Supply Chain Enterprise violated 21 U.S.C. § 483(a)(4), which makes it unlawful "for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter," and a violation of which is punishable by up to four years in jail, *see* 21 U.S.C. § 483(d)(1), making it a felony.

600. The Supply Chain Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the reality of the suspicious orders that the Supply Chain Defendants were filling on a daily basis – leading to the diversion of hundreds of millions of doses of prescriptions opioids into the illicit market.

601. The Supply Chain Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in distributing prescription opioids.

602. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding distribution of prescription opioids and refusing to report suspicious orders.

603. As described herein, the Supply Chain Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

604. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured the County's business and property, while simultaneously generating billion-dollar revenue and profits for the Supply Chain Defendants. The predicate acts were committed or

caused to be committed by the Supply Chain Defendants through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

605. The pattern of corrupt activity alleged herein and the Opioid Supply Chain Enterprise are separate and distinct from each other. Likewise, the Supply Chain Defendants are distinct from the enterprise.

606. The pattern of corrupt activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

607. Many of the precise dates of the Supply Chain Defendants' criminal actions at issue here have been hidden by Defendants and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioid Supply Chain Enterprise alleged herein depended upon secrecy.

608. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of corrupt activity.

609. As evidence of addiction and abuse of opioids widened, Defendants were obligated to rein in their supply, prevent diversion, and mitigate the harms from opioid overuse and abuse, but intentionally and unreasonably failed to do so.

610. It was foreseeable to the Supply Chain Defendants that the County would be harmed when they refused to report and halt suspicious orders, because their violation of their duties imposed by statute and regulation allowed the widespread diversion of prescription opioids out of appropriate medical channels and into the illicit drug market – causing the opioid epidemic that the CSA, as well as Ohio law, intended to prevent.

611. The last incident of corrupt activity occurred within five years of the commission of a prior incident of corrupt activity.

612. For over a decade, the Supply Chain Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the Supply Chain Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Under Ohio law and as "registrants" under the Controlled Substances Act, 21 U.S.C. § 821, *et seq.* (the "CSA"), the Supply Chain Defendants operated and continue to operate within a "closed-system." The CSA and Ohio law restrict the Supply Chain Defendants' ability to distribute Schedule II substances, like opioids, including by requiring them to maintain effective controls against diversion of the controlled substances that they distribute and to design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA.

613. As alleged above, Congress created a closed-system when it enacted the CSA, with the specific intent to protect public safety by reducing or eliminating the diversion of Schedule II drugs, like opioids, from legitimate channels of trade to illicit markets "by controlling the basic ingredients needed for the manufacture of [controlled substances.]"[163] Ohio law is no less stringent. Each of the Supply Chain Defendants knows and has known for decades that if they do not report, investigate or halt suspicious orders, the likelihood of the DEA learning of these illicit transactions and diversions in a timely manner, or at all, is greatly reduced.

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[163] 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf)

614. As described above, the County's allegations in this Count are based on violations of each of the legal duties, statutes, and regulations described in this Complaint, including the violations of Ohio laws and regulations.

615. Finding it impossible to legally achieve their ever increasing sales ambitions, members of the Opioid Supply Chain Enterprise engaged in the common purpose of fraudulently increasing profits from the manufacture and distribution of their prescription opioids. The Supply Chain Defendants formed and pursued their common purpose through the many personal interactions that they had, confidentially, in organizations like the Pain Care Forum and the Healthcare Distribution Alliance.

616. The Supply Chain Defendants' common purpose and fraudulent scheme to unlawfully increase their sales and profits violated the Corrupt Practices Act in three ways. First, the Supply Chain Defendants violated the Corrupt Practices Act because they engaged in the felonious distribution, selling, or otherwise dealing in controlled substances that are punishable by law in the United States. Specifically, the Supply Chain Defendants engaged in the distribution of controlled substances in violation of 21 U.S.C. § 843 because they furnished false or fraudulent material information in, and omitted material information from, applications, reports, records, and other document they were required to make, keep, or file under required to be made, kept, or filed under this subchapter or subchapter II of 21 U.S.C. 801, *et seq*.

617. Second, the Supply Chain Defendants violated the Corrupt Practices Act by engaging in mail and wire fraud. The Supply Chain Defendants' common purpose and fraudulent scheme was intended to, and did, utilize interstate mail and wire facilities for the commission of their fraud in violation 18 U.S.C. §§ 1341 (mail fraud) and 1343 (wire fraud).

618. Third, the Supply Chain Defendants violated the Corrupt Practices Act by engaging in telecommunications fraud. The Supply Chain Defendants' common purpose and fraudulent scheme was intended to, and did disseminate or transmit writings, data, signs, signals, pictures, sounds or images by means of wire, radio, satellite, telecommunication, telecommunications devices or services in furtherance of the scheme to defraud.

619. The Supply Chain Defendants engaged in systematic and fraudulent acts as part of the Opioid Supply Chain Enterprise, that furnished false or fraudulent material information in, and omitted material information from their applications, reports, records and other documents that the Supply Chain Defendants were required to make, keep and/or file. Furthermore, the Supply Chain Defendants engaged in systematic and fraudulent acts as part of the Opioid Supply Chain Enterprise that were intended to and actually did utilize the mail and wire facilities of the United States and Ohio, including refusing to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders.

620. Through the Supply Chain Defendants' scheme, members of the Opioid Supply Chain Enterprise misrepresented that they were complying with their duties under the CSA and Ohio law, furnished false or fraudulent material information in, and omitted material information from their applications, reports, records and other documents, engaged in unlawful sales of painkillers that resulted in diversion of controlled substances through suspicious orders, and refused to identify or report suspicious orders of controlled substances sales to the DEA. Defendants' refusal to report suspicious orders resulted in artificial and illegal increases in opioid sales and distribution. The end result of the Supply Chain Defendants' fraudulent scheme and

common purpose was continually increasing sales and generating obscene profits and, in turn, fueled an opioid epidemic.

B. Impact of The Opioid Supply Chain Enterprise

621. The factual allegations and tragic statistics of injury and damage set forth above apply equally here.

C. Injury Caused and Relief Sought

622. The Supply Chain Defendants' violations of law and their pattern of corrupt activity directly and indirectly caused the County's injury. Their pattern of corrupt activity logically, substantially and foreseeably caused an opioid epidemic. The County's injuries, as described below, were not unexpected, unforeseen or independent. Rather, as the County alleges, Defendants knew that the opioids were going to fuel and ever-increasing illicit prescription market, as well as increasing addiction and death as a result of licit prescriptions of opioids to treat chronic, long-term pain.

623. It was foreseeable and expected that flooding the illegal market for opioids would lead to a nationwide opioid epidemic. It was also foreseeable and expected that it would lead to increased opioid addiction and overdose. The County's injury was logically, foreseeable, and substantially caused by the opioid epidemic that the Supply Chain Defendants created.

624. Specifically, the Supply Chain Defendants' pattern of corrupt activity caused the opioid epidemic which has injured the County in the form of substantial losses of money and property that logically, directly and foreseeably arise from the opioid-addiction epidemic.

625. The County's injuries, as alleged throughout this complaint, and expressly incorporated herein by reference, include:

a. Losses caused by the decrease in funding available for the County's public services for which funding was lost because it was diverted to other public services designed to address the opioid epidemic;

b. Costs for providing healthcare and medical care, additional therapeutic, and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

c. Costs of training emergency and/or first responders in the proper treatment of drug overdoses;

d. Costs associated with providing police officers, firefighters, and emergency and/or first responders with Naloxone – an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

e. Costs associated with emergency responses by police officers, firefighters, and emergency and/or first responders to opioid overdoses;

f. Costs for providing mental-health services, treatment, counseling, rehabilitation services, and social services to victims of the opioid epidemic and their families;

g. Costs for providing treatment of infants born with opioid-related medical conditions, or born addicted to opioids due to drug use by mother during pregnancy;

h. Costs associated with law enforcement and public safety relating to the opioid epidemic, including but not limited to attempts to stop the flow of opioids into local communities, to arrest and prosecute street-level dealers, to prevent the current opioid epidemic from spreading and worsening, and to deal with the increased levels of crimes that have directly resulted from the increased homeless and drug-addicted population;

i. Costs associated with increased burden on the County's judicial system, including increased security, increased staff, and the increased cost of adjudicating criminal matters due to the increase in crime directly resulting from opioid addiction;

j. Costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation;

k. Loss of tax revenue due to the decreased efficiency and size of the working population in the County;

l. Losses caused by diminished property values in neighborhoods where the opioid epidemic has taken root; and

m. Losses caused by diminished property values in the form of decreased business investment and tax revenue.

626. The County seeks all legal and equitable relief as allowed by law, including, *inter alia,* actual damages; treble damages; equitable and/or injunctive relief, including corrective statements, information and education, under R.C. § 2923.34(B)(1)-(2), requiring divestiture by, and reasonable restrictions upon, the future activities of the Defendants; forfeiture as deemed proper by the Court; attorney's fees and all costs; expenses of suit; and pre- and post-judgment interest, as the Court deems just and applicable.

Count VI
Negligence
(Against All Defendants)
(Brought by the County of Fayette, the Plaintiff in this Count)

627. The County incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

628. Defendants owed the County a duty, including a preexisting duty, to not expose the County to an unreasonable risk of harm.

629. Defendants had a legal duty to exercise reasonable and ordinary care and skill in accordance with applicable standards of conduct in manufacturing, advertising, marketing, selling, dispensing, and/or distributing opioids.

630. As evidence of addiction and abuse of opioids widened, Defendants were obligated to rein in their supply, prevent diversion, and mitigate the harms from opioid overuse and abuse.

631. Defendants had a duty not to breach the standard of care established under Ohio law and the federal Controlled Substances Act ("CSA") and its implementing regulations to report suspicious prescribing and to maintain systems to detect and report such activity.

632. The degree of care the law requires is commensurate with the risk of harm the conduct creates. Defendants' conduct in marketing, distributing, dispensing, and selling dangerously addictive drugs requires a high degree of care and places them in a position of great trust and responsibility *vis a vis* The County . Their duty cannot be delegated.

633. Each Defendant breached its duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in selling dangerous controlled substances.

634. Defendants breached their duty to the County by, *inter alia*:

a. Distributing, dispensing, and/or selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing, dispensing, and/or selling opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to effectively monitor for suspicious orders;

d. Choosing not to investigate suspicious orders;

e. Choosing not to report suspicious orders;

f. Choosing not to stop or suspend shipments of suspicious orders; and

g. Distributing, dispensing, and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

635. The Marketing Defendants breached their duty to the County by deceptively marketing opioids, including minimizing the risks of addiction and overdose and exaggerating the purported benefits of long-term use of opioids for the treatment of chronic pain.

636. The County does not allege that Defendants were negligent only for failure to protect from harm. Rather, Defendants engaged in conduct the foreseeable result of which was to cause harm to the County.

637. Defendants have engaged in affirmative acts of creating an illegal, secondary prescription opioid market by failing to exercise adequate control over the marketing, distribution, dispensing, and sale of their prescription opioids.

638. Defendants were negligent by marketing, distributing, dispensing, and/or selling opioids in a way that created and fostered an illegal, secondary prescription opioid market that resulted in a foreseeable and unreasonable risk of harm to the County.

639. The method by which Defendants created this market was by marketing, distributing, dispensing, and/or selling opioids without regard to the likelihood that the opioids would be placed in the hands of criminals, addicts, juveniles, and others not permitted to use or possess prescription opioids.

640. A reasonably prudent opioid manufacturer or distributor, or a reasonably prudent pharmacy, should have anticipated an injury to the County as a probable result of marketing, distributing, dispensing, and/or selling prescription opioids in this manner.

641. It was reasonably foreseeable that Defendants' actions and omissions would result in the harm to the County as described herein.

642. Defendants had control over their conduct in the County. Marketing Defendants controlled their deceptive advertising and efforts to mislead the public, including their acts and omissions in detailing by their sales representatives, online communications, publications, Continuing Medical Education programs and other speaking events, and other means described in this Complaint. All Defendants had control over their own shipments of opioids and over their reporting, or lack thereof, of suspicious prescribers and orders. The Chain Pharmacies controlled their dispensing of opioids. Each of the Defendants controlled the systems it developed to prevent

diversion, and whether it filled orders it knew or should have known were likely to be diverted or fuel an illegal market.

643. Because of the Marketing Defendants' deceptive marketing of opioids and each of the Defendants' special positions within the closed system of opioid distribution, without Defendants' actions, opioid use would not have become so widespread, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

644. Defendants also misleadingly portrayed themselves as cooperating with law enforcement and actively working to combat the opioid epidemic when, in reality, Defendants failed to satisfy even their minimum, legally-required obligations to report suspicious orders. Defendants voluntarily undertook duties, through their statements to the media, regulators, and the public at large, to take all reasonable precautions to prevent drug diversion.

645. Defendants are in the business of manufacturing, marketing, selling, dispensing, and/or distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous because *inter alia* these drugs are defined under federal and state law as substances posing a high potential for abuse and addiction.

646. Indeed, opioids are akin to medical grade heroin. Defendants' wrongful conduct of deceptively marketing and pushing as many opioids onto the market as possible led directly to the public nuisance and harm to the County – exactly as would be expected when medical grade heroin in the form of prescription opioids are deceptively marketed, flood the community, and are diverted into an illegal, secondary market.

647. Reasonably prudent manufacturers of prescription opioids, and reasonably prudent pharmacies, would have anticipated that the scourge of opioid addiction would wreak havoc on

communities, and the significant costs which would be imposed upon the governmental entities associated with those communities. Indeed, it is a violation of R.C. § 4729.35 and O.A.C. §§ 4729-9-12, 4729-9-16, and 4729-9-28 for distributors (including Defendant manufacturers who are also registered as distributors) and a violation of R.C. § 4729.35, 21 U.S.C. § 823, and 21 C.F.R. § 1301.74 for Defendants not to report suspicious orders and exercise due diligence not to ship such orders unless and until the suspicion has been removed. In addition, it is a violation of both Ohio and federal law for a pharmacist to shirk the responsibility to assess the legitimacy of a prescription before filling it. *See* O.A.C. §§ 4729-5-20, 4729-5-21, and 4729-5-30; 21 C.F.R. § 1301.71(a); 21 C.F.R. § 1306.04(a). The closed system of opioid distribution, whereby wholesale distributors are the gatekeepers between manufacturers and pharmacies, exists for the purpose of controlling dangerous substances such as opioids and preventing diversion and abuse.

648. Defendants knew or should have known, that their affirmative misconduct in engaging in an aggressive, widespread, and misleading campaign in marketing narcotic drugs created an unreasonable risk of harm. Defendants' sales data, reports from sales representatives, observations of prescriptions, and internal documents, should have put them on notice that such harm was not only foreseeable, but was actually occurring. Defendants nevertheless chose to deceptively withhold information about the dangers of opioids from the County, physicians, patients, and the public.

649. Defendants conduct was negligence *per se* in that Defendants violated federal law, including, but not limited to, 21 U.S.C. §§ 823 and 827(d)(1); 21 C.F.R. §§ 1301.71, 1301.74, 1304.21, 1304.22, 1304.33(e), and 1306.04; and Ohio law, including, but not limited to, R.C. § 2925.02(A); and § 4729.01(F), R.C. §§ 4729.51-4729.53, O.A.C. §§ 4729-9-12, 4729-9-16, 4729-9-28, 4729-5-20, 4729-5-21, and 4729-5-30. The County was a party intended to be protected by

such laws and whose injuries said laws were designed to prevent. Defendants' violations of said laws proximately caused injury to the County.

650. Defendants also violated federal and Ohio statutes and regulations, including the controlled substances laws, by, *inter alia*:

a. Distributing, dispensing, and/or selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b. Distributing, dispensing, and/or selling opioids without maintaining effective controls against the diversion of opioids;

c. Choosing not to effectively monitor for suspicious orders;

d. Choosing not to investigate suspicious orders;

e. Choosing not to report suspicious orders;

f. Choosing not to stop or suspend shipments of suspicious orders; and

g. Distributing, dispensing, and/or selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

651. As a direct and proximate result of Defendants' negligence and/or negligence *per se*, the County has suffered and will continue to suffer economic damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections, rehabilitation, and other services.

652. As a direct and proximate result of Defendants' negligence and/or negligence *per se*, the County has suffered and will continue to suffer stigma damage, non-physical property damage, and damage to its proprietary interests.

653. As a direct and proximate result of Defendants' negligent, willful, wanton, and intentional acts, omissions, misrepresentations and otherwise culpable acts, there is now a national opioid epidemic that has caused enormous harm and injury to the public, and of which Fayette

County has been uniquely and particularly impacted as a community at the epicenter of the epidemic.

654. Defendants' misconduct alleged in this case is ongoing and persistent.

655. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The County alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

656. The County has incurred expenditures for special programs over and above its ordinary public services.

657. The County has suffered an indivisible injury as a result of the tortious conduct of Defendants.

658. The tortious conduct of each Defendant was a substantial factor in producing harm to the County.

659. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

660. The County seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

Count VII
Injury Through Criminal Acts
(R.C. § 2307.60)
(Against All Defendants)
(Brought by the County of Fayette, the Plaintiff in this Count)

661. The County incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

662. R.C. § 2307.60(A)(1) provides that:

> Anyone injured in person or property by a criminal act has, and may recover full damages in, a civil action unless specifically excepted by law, may recover the costs of maintaining the civil action and attorney's fees if authorized by any provision of the Rules of Civil Procedure or another section of the Revised Code or under the common law of this state, and may recover punitive or exemplary damages if authorized by section 2315.21 or another section of the Revised Code.

663. In the distribution and sale of opioids in Fayette County, Defendants violated R.C. § 2925.02(A), which states:

664. "No person shall knowingly do any of the following:

> (1) By force, threat, or deception, administer to another or induce or cause another to use a controlled substance; . . . or
>
> (3) By any means, administer or furnish to another or induce or cause another to use a controlled substance, and thereby cause serious physical harm to the other person, or cause the other person to become drug dependent."

665. Marketing Defendants' actions in deceptively marketing opioids, as described throughout this Complaint, knowingly induced or caused members of the Fayette County community to use a controlled substance by deception, in violation of R.C. § 2925.02(A).

666. Through the Defendants' actions as described in this Complaint, including flooding the market with opioids, and deliberately disregarding their obligations to maintain effective controls against diversion, Defendants furnished to residents of the County or induced or caused residents of the County to use a controlled substance, thereby causing serious physical harm to those persons and causing them to become drug dependent, in violation of R.C. §§ 2925.02(A)(3).

667. The exemption in R.C. § 2925.02 only applies to drug manufacturers, wholesalers, and pharmacies when their "conduct is in accordance with Chapters R.C. § 3719., 4715., 4723.,

4729., 4730., 4731., and 4741." R.C. § 2925.02(B). Defendants are not in compliance with said Chapters and have thereby forfeited the protection provided by the exception.

668. In the distribution and sale of opioids in Ohio and the County, Defendants violated R.C. § 2925.02(A)(2), which makes it a crime to: "Prepare for shipment, ship, transport, deliver, prepare for distribution, or distribute a controlled substance or a controlled substance analog, when the offender knows or has reasonable cause to believe that the controlled substance or a controlled substance analog is intended for sale or resale by the offender or another person."

669. Defendants may claim an exemption to R.C. § 2925.03(A)(2) only if their "conduct is in accordance with Chapters 3719., 4715., 4723., 4729., 4730., 4731., and 4741. of the Revised Code." Defendants are not in compliance with said Chapters and have thereby forfeited the protection provided by the exception.

670. Defendants have engaged in additional criminal acts detailed in the Ohio Corrupt Practices Act Counts above, including acts of criminal wire fraud, mail fraud, telecommunications fraud, unlawful dealing in controlled substances, and violations of the Ohio Corrupt Practices Act.

671. It was foreseeable to Defendants that their misconduct alleged in this Count would lead to addiction, abuse, misuse, and diversion of opioids, both in Fayette County and throughout the United States.

672. The County was within the zone of interest protected by these criminal laws.

673. As a direct and proximate result of Defendants' criminal acts as described in this Count, the County suffered injury and damages, for which the County is entitled to recover pursuant to R.C. § 2307.60(A)(1).

674. Defendants' misconduct alleged in this case is ongoing and persistent.

675. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The County alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

676. The County has incurred expenditures for special programs over and above its ordinary public services.

677. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions had a great probability of causing substantial harm.

678. The County seeks all legal relief to which they may be entitled pursuant to R.C. § 2307.60(A)(1), including *inter alia* compensatory damages, punitive and/or exemplary damages, attorney's fees, and the costs and expenses of suit, including pre- and post-judgment interest.

Count VIII
Unjust Enrichment
(Against All Defendants)
(Brought by the County of Fayette, the Plaintiff in this Count)

679. The County incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

680. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from the increase in the distribution and purchase of opioids within the County, including from opioids foreseeably and deliberately diverted within and into Fayette County.

681. Unjust enrichment arises not only where an expenditure by one party adds to the property of another, but also where the expenditure saves the other from expense or loss.

682. The County has expended substantial amounts of money in an effort to remedy or mitigate the societal harms caused by Defendants' conduct.

683. These expenditures include the provision of healthcare services and treatment services to people who use opioids.

684. These expenditures have helped sustain Defendants' businesses.

685. The County has conferred a benefit upon Defendants by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper marketing, distribution and dispensing practices.

686. Defendants were aware of these obvious benefits, and their retention of the benefit is unjust.

687. The County has paid for the cost of Defendants' externalities and Defendants have benefited from those payments because they allowed them to continue providing customers with a high volume of opioid products. Because of their deceptive marketing of prescription opioids, Marketing Defendants obtained enrichment they would not otherwise have obtained. Because of their conscious failure to exercise due diligence in preventing diversion, Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and the County lacks a remedy provided by law.

688. Defendants have unjustly retained benefits to the detriment of the County, and Defendants' retention of such benefits violates the fundamental principles of justice, equity, and good conscience.

689. Defendants' misconduct alleged in this case is ongoing and persistent.

690. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not

part of the normal and expected costs of a local government's existence. The County alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

691. The County has incurred expenditures for special programs over and above the County's ordinary public services.

692. The County seeks an order compelling Defendants to disgorge all unjust enrichment to the County; and awarding such other, further, and different relief as this Honorable Court may deem just.

Count IX
Civil Conspiracy
(Against All Defendants)
(Brought by the County of Fayette, the Plaintiff in this Count)

693. The County incorporates by reference all other paragraphs of this Complaint as if fully set forth herein, and further alleges:

694. Defendants engaged in a civil conspiracy in their unlawful marketing of opioids and/or distribution and/or dispensing of opioids into Fayette County.

695. Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in conjunction with their unlawful marketing, distribution, and/or dispensing of opioids into the County.

696. Defendants unlawfully failed to act to prevent diversion and failed to monitor for, report, and prevent suspicious orders of opioids.

697. The Marketing Defendants further unlawfully marketed opioids in the County in furtherance of that conspiracy.

698. Defendants' conspiracy and acts in furtherance thereof are alleged in detail in this Complaint, including, without limitation, in the County's Counts for violations of the Ohio Corrupt Practices Act. Such allegations are specifically incorporated herein.

699. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, which directly caused the injuries alleged herein.

700. Defendants acted with malice, purposely, intentionally, unlawfully, and without a reasonable or lawful excuse.

701. Defendants conduct in furtherance of the conspiracy described herein was not mere parallel conduct because each Defendant acted directly against their commercial interests in not reporting the unlawful distribution or dispensing practices of their competitors to the authorities. Each Defendant acted against their commercial interests in this regard due to an actual or tacit agreement between the Defendants that they would not report each other to the authorities so they could all continue engaging in their unlawful conduct.

702. Defendants' conspiracy, and Defendants' actions and omissions in furtherance thereof, caused the direct and foreseeable losses alleged herein.

703. Defendants' actions demonstrated both malice and also aggravated and egregious fraud. Defendants engaged in the conduct alleged herein with a conscious disregard for the rights and safety of other persons, even though that conduct had a great probability of causing substantial harm. Marketing Defendants' fraudulent wrongdoing was done with a particularly gross and conscious disregard.

704. Defendants' misconduct alleged in this case is ongoing and persistent.

705. Defendants' misconduct alleged in this case does not concern a discrete event or discrete emergency of the sort a political subdivision would reasonably expect to occur, and is not part of the normal and expected costs of a local government's existence. The County alleges wrongful acts which are neither discrete nor of the sort a local government can reasonably expect.

706. The County has incurred expenditures for special programs over and above its ordinary public services.

707. The County seeks all legal and equitable relief as allowed by law, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre-and post-judgment interest.

PRAYER FOR RELIEF

WHEREFORE, the County requests the following relief:

A. A finding that, by the acts alleged herein, Defendants have created a public nuisance;

B. An injunction permanently enjoining Defendants from engaging in the acts and practices that caused the public nuisance;

C. An order directing Defendants to abate the public nuisance;

D. A finding that, by the acts alleged herein, Defendants violated the Ohio Corrupt Practices Act ("OCPA"), R.C. 2923.31, *et seq.*;

E. A finding that, by the acts alleged herein, Defendants violated R.C. 2307.60;

F. An award of three times the County's actual damages under R.C. 2923.31, *et seq.*;

G. Compensatory damages in an amount in excess of $25,000 sufficient to fairly and completely compensate for all damages alleged herein;

H. Punitive damages in excess of $25,000;

I. Disgorgement of Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein;

J. For costs, filing fees, pre and post judgment interest, and attorney's fees; and

K. For all other relief at law or in equity, deemed just by this Court.

Respectfully submitted,

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JURY DEMAND

Plaintiff requests a jury be seated to try all issues of fact and law presented herein.

Jess Weade